Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2017

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

I, Allison Jones, a delegate of the Minister for Health and Aged Care for the purposes of subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act), **HEREBY**:

(a) Revoke the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2016; and

(b) Make the following determination specifying:

(i) ingredients for the purposes of paragraph 26BB(1)(a) of the Act; and

(ii) requirements applying to those ingredients for the purposes of paragraph 26BB(1)(b) of the Act.

Dated this 16 January 2017

(Signed by)

Allison Jones
Delegate of the Minister for Health and Aged Care

1 Name of Determination

This Determination is the *Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2017*.

2 Commencement

This Determination commences on the day after registration of the instrument on the Federal Register of Legislation.

3 Interpretation

In this Determination:

Act means the *Therapeutic Goods Act 1989*.

Code Tables are tables that can be accessed from the Therapeutic Goods Administration Business Service website at www.ebs.tga.gov.au under the heading "Public TGA Information".

European Pharmacopoeia is as defined under the Act.

Mandatory component is a naturally occurring constituent in a specified ingredient listed in column 2 of Table 1 of Schedule 1 to this Determination.

4 Permissible ingredients and requirements applying to those ingredients

Permissible ingredients and requirements applying to those ingredients under Table 1

(1) The ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1 (Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine) to this Determination (Schedule 1) are specified for the purposes of paragraph 26BB(1)(a) of the Act.

(2) Subject to subsection (3), for the purposes of paragraph 26BB(1)(b) of the Act, the ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1 are subject to the following requirements:

(a) they may only be used in a medicine for a purpose or purposes specified in column 3 of Table 1 in Part 2 of Schedule 1; and

(b) they must comply with the requirements set out in column 4 of Table 1 in Part 2 of Schedule 1.

(3) The requirements set out in column 4 in relation to a mandatory component of an ingredient listed in column 2 of Table 1 in Part 2 of Schedule 1 apply to that specified ingredient.

Indications and Product Warning Acronyms based on the electronic Code Table document

(4) The acronyms in column 4 of Table 1 in Part 2 of Schedule 1 in closed brackets that are associated with warning statements in relation to particular ingredients

specified in column 2 of Table 1 in Part 2 of Schedule 1, are acronyms from the Code Tables under the headings "Indications" or "Product Warning" and are not required to be included on the label of the medicine.

Note: Examples of these acronyms are:

(CHILD3), (PREGNT), (GLUTEN), (PEANUT) and (ARGIN1).

Additional requirements applying to specified ingredients in Table 1 that are derived from animal origins

(5) Ingredients specified in column 2 of Table 1 in Part 2 of Schedule 1 that are derived from animal origins (non-human) must also comply with the following requirements, for the purposes of paragraph 26BB(1)(b) of the Act:

(a) a certification must be obtained under subsection 26A(4A) of the Act from the Secretary, prior to an application being made for the listing in the Australian Register of Therapeutic Goods, under section 26A of the Act, of a medicine that contains the ingredient, that the Secretary is satisfied of the safety of the ingredient;

(b) the safety of the ingredient must have been assessed against the principles and requirements detailed in the European Pharmacopoeia general monograph 1483: *Products with risk of transmitting agents of animal spongiform encephalopathies*, including General Text 5.2.8: *Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.*

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 1—Interpretation of Table 1

Definitions

At Table 1:

"***A***" means an active ingredient.

Act means the *Therapeutic Goods Act 1989*.

Active ingredient is as defined in the Regulations.

British Pharmacopoeia is as defined under the Act.

"E" means an excipient.

Excipient means an ingredient that is not an active ingredient or a homoeopathic preparation ingredient.

Note: An excipient includes an ingredient that provides flavour, fragrance or colour to the medicine.

"H" means a homoeopathic preparation ingredient.

Homoeopathic preparation ingredient means an ingredient that is a constituent of a preparation that is:

(a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and

(b) prepared according to the practices of homoeopathic pharmacy using the methods of:

(i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or

(ii) serial trituration in lactose.

Mother tincture is as defined in the Regulations.

Regulations means the Therapeutic Goods Regulations 1990.

United States Pharmacopeia-National Formulary is as defined under the Act.

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1	(1,7,7-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2	(1R,2S,5R)-N-(4-METHOXYPHENYL)-5-METHYL-2-(1-METHYLETHYL) CYCLOHEXANECARBOXAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
3	(E)-2-(3,5-DIMETHYLHEX-3-EN-2-YLOXY)-2-METHYLPROPYL CYCLOPROPANECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4	(E)-3-METHYLCYCLOPENTADEC-5-EN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5	(E, E)-2,6-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
6	(S)- LACTIC ACID	A,E,H	
7	(S)-S-ADENOSYLMETHIONINE DISULFATE DITOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
8	(S)-S-ADENOSYLMETHIONINE DISULFATE TOSYLATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine disulfate tosilate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
9	(S)-S-ADENOSYLMETHIONI	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-

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	NE DISULFATE TRITOSYLATE DIHYDRATE		Adenosylmethionine disulfate tritosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
10	(S)-S-ADENOSYLMETHIONINE HEXASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
11	(S)-S-ADENOSYLMETHIONINE HEXATOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine hexatosylate dihydrate and must be declared in the application. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the

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			following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
12	(S)-S-ADENOSYLMETHIONINE PENTASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: -(SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
13	(S)-S-ADENOSYLMETHIONINE PENTATOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine pentatosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the

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			supervision of a healthcare practitioner (or words to that effect)'
14	(S)-S-ADENOSYLMETHIONINE TETRASULFATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetrasulfate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
15	(S)-S-ADENOSYLMETHIONINE TETRATOSYLATE DIHYDRATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine tetratosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
16	(S)-S-ADENOSYLMETHIONINE TRISULFATE DITOSYLATE	A	(S)-S-Adenosylmethionine is a mandatory component of (S)-S-Adenosylmethionine trisulfate

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	DIHYDRATE		ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
17	(Z)-HEX-3-ENYL 2-ETHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
18	(Z, Z)-3,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
19	(±)-NARINGENIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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20	1-(2,2,6-TRIMETHYLCYCLOHEXYL)-3-HEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
21	1-(2,6,6-TRIMETHYL-2-CYCLOHEXEN-1-YL)-1-PENTEN-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
22	1-(3,3-DIMETHYLCYCLOHEXYL)ETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
23	1-(4-ISOPROPYLCYCLOHEXYL)ETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
24	1-(5,5-DIMETHYL-1-CYCLOHEXEN-1-YL)-4-PENTEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
25	1-DODECANOL	E	Only for use in topical medicines for dermal application.

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26	1-HEPTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
27	1-HEXEN-3-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
28	1-METHOXY-4-PROPENYLBENZENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
29	1-METHYL-2-[(1,2,2-TRIMETHYLBICYCLO[3.1.0]HEX-3-YL)METHYL]-CYCLOPROPANEMETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
30	1-METHYL-3-(2-METHYLPROPYL)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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31	1-METHYL-4-(4-METHYL-3-PENTENYL)-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
32	1-OCTEN-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
33	1-P-MENTHENE-8-THIOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
34	1-PENTEN-3-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
35	1,1,1-TRICHLOROETHANE	E	The concentration in the medicine must be no more than 25%.
36	1,2-HEXANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%.

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37	1,3-BUTYLENE GLYCOL	E	
38	1,3-NONANEDIOL ACETATE, MIXED ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
39	1,3-NONANEDIOL, DIACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
40	1,3,4,6,7,8A-HEXAHYDRO-1,1,5,5-TETRAMETHYL-2H-2,4A-METHANONAPHTHALEN-8(5H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
41	1,3,5-UNDECATRIENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
42	1,4-CINEOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%
43	1,4-DIOXACYCLOHEXADECANE-5,16-DIONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
44	1,5,9-TRIMETHYL-13-OXABICYCLO[10.1.0]TRIDECA-4,8-DIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
45	1,7,7-TRIMETHYLBICYCLO[4.4.0]DECAN-3-YL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
46	10-UNDECEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
47	10-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
48	16-HYDROXY-12-OXAHEXADECANOIC ACID, OMEGA-LACTONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
49	2-(1,1-DIMETHYLETHYL)-1,4-DIMETHOXY-BENZENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
50	2-(2-(4-METHYL-3-CYCLOHEXEN-1-YL)PROPYL CYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
51	2-ACETYLFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
52	2-ACETYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
53	2-ACETYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
54	2-AMINO-2-METHYL-1-PROPANOL	E	Only for use in topical medicines for dermal application.
55	2-BENZYL-4,4,6-TRIMETHYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
56	2-BUTEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
57	2-BUTYL-4,4,6-TRIMETHYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
58	2-CYCLOHEXYLIDENE-2-O-TOLYL-ACETONITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
59	2-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
60	2-DODECANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
61	2-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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62	2-ETHOXY-4-(METHOXYMETHYL)-PHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
63	2-ETHOXYETHANOL	E	The residual solvent limit for 2-Ethoxyethanol is 1.6 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.016%.
64	2-ETHYL-1-HEXANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
65	2-ETHYL-3-METHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
66	2-ETHYL-3,5-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
67	2-ETHYL-3,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
68	2-ETHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-2-BUTEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
69	2-ETHYL-4-HYDROXY-5-METHYL-3(2H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
70	2-ETHYL-4-METHYLTHIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
71	2-ETHYL-ALPHA,ALPHA-DIMETHYL-	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	BENZENEPROPANAL		If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
72	2-ETHYL METHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
73	2-ETHYLBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
74	2-HEPTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
75	2-HEPTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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76	2-HEPTYL CYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
77	2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
78	2-ISOBUTYL-3-METHOXYPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
79	2-ISOBUTYL-4-METHYLTETRAHYDRO-2H-PYRAN-4-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
80	2-ISOPROPOXYETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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81	2-ISOPROPYL-4-METHYLTHIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
82	2-MERCAPTOPROPIONIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
83	2-METHOXY-3-SECBUTYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
84	2-METHOXY-4-VINYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
85	2-METHYL-2-PENTENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
86	2-METHYL-2-VINYL-5-ISOPROPENYLTETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
87	2-METHYL-3-(3,4-METHYLENEDIOXYPHENYL)PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
88	2-METHYL-3-(4-METHOXYPHENYL)PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
89	2-METHYL-3-BUTEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
90	2-METHYL-3-FURANTHIOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
91	2-METHYL-3-[4-(2-METHYLPROPYL)PHENYL]PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
92	2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)BUTANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
93	2-METHYL-4-(2,2,3-TRIMETHYL-3-CYCLOPENTENYL)-2-BUTEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%. Only for use in topical medicines for dermal application.
94	2-METHYL-4-(2,6,6-TRIMETHYL-1-CYCLOHEXEN-1-YL)-2-BUTENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
95	2-METHYL-4-(CAMPHENYL-8)-CYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
96	2-METHYL-4-PROPYL-1,3-OXTHIANE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
97	2-METHYL-5-(METHYLTHIO)FURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
98	2-METHYL-5-PHENYLPENTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
99	2-METHYL BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
100	2-METHYL HEPTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
101	2-METHYLBUTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
102	2-METHYLBUTYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
103	2-METHYLBUTYL PHENYLETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
104	2-METHYLBUTYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
105	2-METHYLHEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
106	2-METHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
107	2-METHYLTETRAHYDROFURAN-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
108	2-METHYLUNDECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
109	2-METHYLVALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
110	2-NONENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
111	2-NONENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
112	2-OXOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
113	2-PENTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
114	2-PENTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
115	2-PENTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
116	2-PENTYL FURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
117	2-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
118	2-PHENYLPROPIONALDEHYDE DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
119	2-PROPENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
120	2-SEC-BUTYL CYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
121	2-TERT-BUTYLCYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
122	2-TERT-BUTYLCYCLOHEXYLOXY-2-BUTANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
123	2-TRANS-6-CIS-NONADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
124	2-TRIDECANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
125	2-TRIDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
126	2-TRIDECENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
127	2-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
128	2-[(3,7-DIMETHYL-6-OCTEN-1-YLIDENE)AMINO]BENZOIC ACID, METHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
129	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-METHYLPROPYL]	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CYCLOPROPANECARBOXYLATE		If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
130	2-[1-(3,3-DIMETHYLCYCLOHEXYL)ETHOXY]-2-OXOETHYL PROPANOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
131	2,2-DIMETHYL-3-(3-METHYL-2,4-PENTADIENYL)-OXIRANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
132	2,2-DIMETHYL-3-PHENYLPROPANOLL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
133	2,2-DIMETHYL-5-(1-METHYLPROPEN-1-YL) TETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
134	2,2-DIMETHYL-P-ETHYLPHENYL-PROPANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
135	2,2,3-TRIMETHYLCYCLOPENT-3-ENE-1-ETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
136	2,2,5-TRIMETHYL-5-PENTYLCYCLOPENTANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
137	2,3-DIETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
138	2,3-DIHYDRO-2,5-DIMETHYL-1H-INDENE-2-METHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
139	2,3-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
140	2,3-HEXADIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
141	2,3-HEXANEDIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
142	2,3-PENTANEDIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
143	2,3,4-TRIMETHYL-3-PENTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
144	2,3,5-TRIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
145	2,3,5,6-TETRAMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
146	2,4-DECADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Decadienal.
147	2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
148	2,4-DIMETHYL-4-PHENYL TETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
149	2,4-DIMETHYL-4,4A,5,9B-TETRAHYDROINDENO[1,2-D]-1,3-DIOXIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
150	2,4-DIMETHYL BUTADIENEACROLEIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
151	2,4-DIMETHYL THIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
152	2,4-HEPTADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 3 mg of 2,4-Heptadienal.
153	2,4-HEXADIENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The maximum daily dose must provide no more than 13.5 mg of 2,4-Hexadienol.
154	2,4,5-TRIMETHYLTHIAZOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
155	2,4,6-TRIMETHYL-4-PHENYL-1,3-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
156	2,5-DIETHYLTETRAHYDROFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
157	2,5-DIMETHYL-2-OCTEN-6-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
158	2,5-DIMETHYL-4-HYDROXY-3(2H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
159	2,5-DIMETHYL-4-METHOXY-3(2H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
160	2,5-DIMETHYLPYRAZINE	E	If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
161	2,6-DIMETHOXYPHENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
162	2,6-DIMETHYL-2-HEPTENAL-(7)	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
163	2,6-DIMETHYL-3,5-OCTADIEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
164	2,6-DIMETHYL-4-HEPTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
165	2,6-DIMETHYL HEPTAN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
166	2,6-DIMETHYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
167	2,6-NONADIEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
168	2,6-OCTADIENOIC ACID, 3,7-DIMETHYL-, METHYL ESTER, (2E)-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
169	2,6,6,TRIMETHYL-2-CYCLOHEXENE-1,4-DIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
170	2,6,9,10-TETRAMETHYL-1-OXASPIRO(4.5)DECA-3,6-DIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
171	3-(3-ISOPROPYLPHENYL)BUTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
172	3-(4-ETHYLPHENYL)-2,2-DIMETHYLPROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
173	3-(4-HYDROXYPHENYL)-1-(2,4,6-TRIHYDROXYPHENYL)-1-PROPANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
174	3-(4-TERT-BUTYLPHENYL)-PROPANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
175	3-(ISO-CAMPHYL-5)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
176	3-(METHYLTHIO)-1-HEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
177	3-CARENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
178	3-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
179	3-ETHYLPYRIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
180	3-HEPTYLDIHYDRO-5-METHYL-2(3H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
181	3-HEXANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
182	3-HEXEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
183	3-ISO-CAMPHYL-5-CYCLOHEXAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
184	3-METHYL-2-(PENTYLOXY)CYCLOPENT-2-EN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
185	3-METHYL-5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-4-PENTEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
186	3-METHYL-5-PHENYL PENT-2-ENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
187	3-METHYL-5-PHENYLPENTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
188	3-METHYL-5-PHENYLPENTANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
189	3-METHYL-5-PHENYLPENTANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
190	3-METHYL-5-PROPYL-2-CYCLOHEXEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
191	3-METHYL THIOPROPIONALDEHYDE ETHANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
192	3-METHYLCYCLOPENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
193	3-METHYLCYCLOPENTADECENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
194	3-METHYLTHIOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
195	3-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
196	3-PENTYLTETRAHYDRO-2H-PYRAN-4-OL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
197	3-PHENYLPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
198	3-PHENYLPROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
199	3-PHENYLPROPYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
200	3-PROPYLIDENE PHTHALIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
201	3-TRANS-ISOCAMPHYLCYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
202	3,3-DIMETHYL-5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	4-PENTEN-2-OL		If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
203	3,3-DIMETHYLACRYLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
204	3,4-DIMETHYL-1,2-CYCLOPENTADIONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
205	3,4,4A,5,8,8A-HEXAHYDRO-3',7-DIMETHYLSPIRO-1,4-METHANONAPHALENE-2(1H),2'-OXIRANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
206	3,5-DIMETHOXYTOLUENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
207	3,5-DIMETHYL-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
208	3,5,5-TRIMETHYL HEXANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
209	3,5,5-TRIMETHYLHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
210	3,5,6,6-TETRAMETHYL-4-METHYLENEHEPTAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
211	3,6-DIMETHYL-3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
212	3,7-DIMETHYL-1-OCTANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
213	3,7-DIMETHYL-2,6-NONADIENENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
214	3,7-DIMETHYL-7-METHOXYOCTAN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
215	3,7-DIMETHYL OCTANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
216	3A,6,6,9A-TETRAMETHYLDODECAHYDRONAPHTHO[2,1-B] FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
217	4-(4-HYDROXY-4-METHYLPENTYL)-3-CYCLOHEXENE CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
218	4-(4-METHYL-3-PENTEN-1-YL)-3-CYCLOHEXENE-1-	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CARBOXALDEHYDE		If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
219	4-(5,5,6-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)-CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
220	4-(METHYLTHIO)-4-METHYL-2-PENTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
221	4-(PARA-HYDROXYPHENYL)-2-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
222	4-(PARA-METHOXYPHENYL)-2-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
223	4-ACETYL-6-TERTIARY-BUTYL-1,1-DIMETHYLINDAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
224	4-ETHYL GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
225	4-HEPTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
226	4-HYDROXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
227	4-HYDROXYBENZYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
228	4-METHOXY-2-METHYL-2-BUTANETHIOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
229	4-METHYL-3-DECEN-5-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
230	4-METHYL-4-MERCAPTOPENTAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
231	4-METHYL-4-PHENYL-2-PENTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
232	4-METHYL-5-THIAZOLETHANOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
233	4-METHYLBENZYLIDENE CAMPHOR	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
234	4-METHYLPENTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
235	4-METHYLPHENYL OCTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
236	4-PARA METHOXYPHENYL-3-BUTANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
237	4-PENTENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
238	4-TERT-BUTYL-2,6-DIMETHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
239	4-TERT-BUTYLCYCLOHEXANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
240	4-TERT-PENTYLCYCLOHEXANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
241	4,4A,5,9B-TETRAHYDRO-2,4-DIMETHYL-INDENO(1,2-D)-1,3-DIOXIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
242	4,4A,5,9B-TETRAHYDROINDENO(1,2-D)-1,3-DIOXIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
243	4,5-DIMETHYL-3-HYDROXY-2(5H)FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
244	4,7-METHANO-3A,4,5,6,7,7A-HEXAHYDRO-5 (OR 6) -INDENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
245	4,8-DIMETHYL-3,7-NONADIEN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
246	5-(2,2,3-TRIMETHYL-3-CYCLOPENTEN-1-YL)-3-METHYLPENTAN-2-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
247	5-ACETYL-1,1,2,3,3,6-HEXAMETHYL INDAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
248	5-CYCLOHEXADECEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
249	5-ETHYL-3-HYDOXY-4-METHYL-2(5H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
250	5-ETHYL-4-HYDROXY-2-METHYL-3(2H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
251	5-HYDROXY-4-METHYLHEXANOIC ACID DELTA-LACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
252	5-METHOXYPSORALEN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
253	5-METHYL-2-THIOPHENE CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
254	5-METHYL-3-BUTYLTETRAHYDROPYRAN-4-YL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
255	5-METHYL-3-HEPTANONE OXIME	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
256	5-METHYL 2-PHENYL HEXEN-2-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
257	5-PENTYL-2(5H)-FURANONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
258	5,6,7,8-TETRAHYDROQUINOXALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
259	5,7-DIHYDRO-2-METHYLTHIENO (3,4D) PYRIMIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
260	6-BUTYL-3,6-DIHYDRO-2,4-DIMETHYL-2H-PYRAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
261	6-METHOXY-2,6-DIMETHYLHEPTAN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
262	6-METHYL-2-BUTEN-3-OL-2	E	
263	6-METHYL COUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
264	6,6-DIMETHOXY-2,5,5-TRIMETHYL-2-HEXENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
265	6,6-DIMETHYL-2-NORPINENEPROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
266	6,7-DIHYDRO-1,1,2,3,3-PENTAMETHYL-4(5H)-INDANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
267	7-ACETYL-1,1,3,4,4,6-HEXAMETHYL TETRAHYDRONAPHTHALENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
268	7-METHYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
269	7-OCTENE-1,6-DIOL, 3,7-DIMETHYL-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
270	7-PROPYL-2H-1,5-BENZODIOXEPIN-3(4H)-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
271	8-METHYL-1-OXASPIRO(4,5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
272	8-OCIMENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
273	8,13:13,20-DIEPOXY-14,15-BISNORLABDANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
274	9-DECEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
275	ABELMOSCHUS MOSCHATUS	A,H	
276	ABELMOSCHUS MOSCHATUS SUBSP. MOSCHATUS	A,H	
277	ABIES BALSAMEA	A,H	
278	ABIES NIGRA	A,H	
279	ABIES PECTINATA	A,H	
280	ABIES SIBIRICA	A,H	
281	ABRUS CANTONIENSIS	A,H	If the herbal substance is derived from the seed, the maximum recommended daily dose of Abrus cantoniensis must be no more than 1mg of the dry seed.
282	ABSIDIA RAMOSA	A,H	
283	ABUTILON THEOPHRASTI	A,H	
284	ACACIA	A,E,H	
285	ACACIA BAILEYANA	A,H	
286	ACACIA CATECHU	A,H	
287	ACACIA DEALBATA	A,H	
288	ACACIA DECURRENS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
289	ACACIA FARNESIANA	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
290	ACACIA LONGIFOLIA	A,E,H	
291	ACACIA NILOTICA	A,E,H	
292	ACACIA SENEGAL	A,E,H	
293	ACALYPHA INDICA	A,H	
294	ACANTHUS MOLLIS	A,H	
295	ACER CAMPESTRE	A,H	
296	ACER NEGUNDO	A,H	
297	ACER SACCHARINUM	A,H	
298	ACER SACCHARUM	A,E,H	
299	ACEROLA	E	
300	ACESULFAME POTASSIUM	E	
301	ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
302	ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
303	ACETALDEHYDE ETHYL LINALYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
304	ACETALDEHYDE ETHYL PHENYLETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
305	ACETALDEHYDE PHENYLETHYL PROPYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
306	ACETANISOLE	E	Only for use in topical medicines for dermal application.
307	ACETIC ACID	E,H	The concentration in the medicine must be no more than 1.5%.
308	ACETOIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
309	ACETOMENAPHTHONE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
310	ACETONE	E	The residual solvent limit for Acetone is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
311	ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
312	ACETOVANILLONE	E	Only for use in topical medicines for dermal application. Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
313	ACETYL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
314	ACETYL DIPEPTIDE-1 CETYL ESTER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
315	ACETYL GLUCOSAMINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%. If the ingredient is sourced from seafood, then the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'
316	ACETYL HEXAMETHYL TETRALIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
317	ACETYL LEVOCARNITINE HYDROCHLORIDE	A,E	
318	ACETYL TRIFLUOROMETHYLPHENYL VALYLGLYCINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
319	ACETYLATED LANOLIN	E	Only for use in topical medicines for dermal application.
320	ACETYLATED LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
321	ACETYLATED MONOGLYCERIDES	E	
322	ACETYLATED VETIVER OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
323	ACETYLCYSTEINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%.
324	ACHILLEA ERBA-ROTTA SUBSP. MOSCHATA	A,H	
325	ACHILLEA MILLEFOLIUM	A,E,H	
326	ACHILLEA PTARMICA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
327	ACHYRANTHES ASPERA	A,H	
328	ACHYRANTHES BIDENTATA	A,H	
329	ACHYRANTHES FAURIEI	A,H	
330	ACID-ISOMERISED LINALOOL	E	
331	ACID GREEN 25	E	Permitted for use as a colour for topical use.
332	ACID RED 33	E	Permitted for use as a colour for topical use.
333	ACID RED 87	E,H	Only for use as an active homoeopathic ingredient or for excipient use as a colour in topical medicines.
334	ACID TREATED WAXY MAIZE STARCH	E	
335	ACONITUM CARMICHAELII	A,H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum carmichaelii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
336	ACONITUM FEROX	A,H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum ferox. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
337	ACONITUM KUSNEZOFFI	A,H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum kusnezoffii. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
338	ACONITUM NAPELLUS	A,H	Total alkaloids (of Aconitum spp.) is a mandatory component of Aconitum napellus. The maximum amount of total alkaloids (of Aconitum spp.) must be no more than 0.02 milligrams per pack.
339	ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.7%.
340	ACRYLAMIDES COPOLYMER	E	Only for use in topical medicines for dermal application.
341	ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
342	ACRYLATES/ACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
343	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
344	ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 5%.
345	ACRYLATES/DIMETHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
346	ACRYLATES/OCTYLACRYLAMIDE COPOLYMER	E	Only for use in topical medicines for dermal application.
347	ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
348	ACRYLATES/VA COPOLYMER	E	Only for use in topical medicines for dermal application.
349	ACRYLIC ACID/VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
350	ACTAEA CIMICIFUGA	A,H	
351	ACTAEA HERACLEIFOLIA	A,H	
352	ACTAEA PACHYPODA	A,H	
353	ACTAEA RACEMOSA	A,H	When used in oral medicines, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
354	ACTAEA SIMPLEX	A,H	
355	ACTAEA SPICATA	A,H	
356	ACTINIDIA CHINENSIS	A,H	
357	ACTINIDIA DELICIOSA	A,H	
358	ACTIVATED ATTAPULGITE	A	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
359	ACTIVATED CHARCOAL	A,E,H	When for internal use, the medicine requires the following warning statement on the medicine label: - (ACCOAL) 'Products containing activated charcoal should be used with caution in children since it may interfere with absorption of nutrients. Activated charcoal may interact with other medicines. Activated charcoal is not recommended for long-term use' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
360	ADEMETIONINE DISULFATE DITOSYLATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate ditosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
361	ADEMETIONINE DISULFATE TOSYLATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine disulfate ditosylate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
362	ADEMETIONINE DISULFATE TRITOSYLATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine trisulfate ditosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
363	ADEMETIONINE HEXASULFATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexasulfate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
364	ADEMETIONINE HEXATOSYLATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine hexatosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
365	ADEMETIONINE PENTASULFATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentasulfate dihydrate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
366	ADEMETIONINE PENTATOSYLATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine pentatosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
367	ADEMETIONINE TETRASULFATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetrasulfate ditosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			supervision of a healthcare practitioner (or words to that effect)'
368	ADEMETIONINE TETRATOSYLATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine tetratosylate dihydrate. Ademetionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
369	ADEMETIONINE TRISULFATE DITOSYLATE DIHYDRATE	A,H	(S)-S-Adenosylmethionine is a mandatory component of Ademetionine trisulfate ditosylate dihydrate. (S)-S-Adenosylmethionine in the form of sulfate tosylate or mixed sulfate/tosylate salts requires the following warning statement on the medicine label: - (SAME) 'Individuals who are using prescription anti-depressants or suffer from bipolar depression should not use this product unless under the supervision of a healthcare practitioner (or words to that effect)'
370	ADENOPHORA STRICTA	A,H	
371	ADENOPHORA TRIPHYLLA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
372	ADENOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.04%.
373	ADENOSINE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
374	ADENOSINE TRIPHOSPHATE	E	Only for use in topical medicines for dermal application.
375	ADENOSINE TRIPHOSPHATE DISODIUM	E	Only for use in topical medicines for dermal application.
376	ADIANTUM CAPILLUS-VENERIS	A,H	
377	ADIPIC ACID	E	
378	ADIPIC ACID/DIETHYLENE GLYCOL/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
379	ADONIS VERNALIS	A,H	The concentration of equivalent dry Adonis vernalis in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
380	ADRENALINE (EPINEPHRINE)	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
381	ADZUKI BEAN	E	
382	AEGOPODIUM PODAGRARIA	A,H	
383	AESCULUS CHINENSIS	A,H	
384	AESCULUS GLABRA	A,H	
385	AESCULUS HIPPOCASTANUM	A,H	
386	AESCULUS X CARNEA	A,H	
387	AETHUSA CYNAPIUM	H	Only for use as an active homoeopathic ingredient.
388	AGAR	A,E	
389	AGASTACHE RUGOSA	A,H	
390	AGATHOSMA BETULINA	A,E,H	Pulegone is a mandatory component of Agathosma betulina. The concentration of pulegone in the medicine must be no more than 4%.
391	AGAVE AMERICANA	A,E,H	
392	AGRIMONIA EUPATORIA	A,E,H	
393	AGRIMONIA REPENS	A,H	
394	AGROSTIS TENUIS	A,H	
395	AILANTHUS ALTISSIMA	A,H	
396	AJUGA CHAMAEPITYS	A,H	
397	AJUGA REPTANS	A,H	
398	ALANINE	A,E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
399	ALANYLGLUTAMINE	A	Only for use in oral medicines.
400	ALARIA ESCULENTA	A,H	Iodine is a mandatory component of Alaria esculenta. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral and sublingual use.
401	ALBIZIA JULIBRISSIN	A,H	
402	ALBIZIA LEBBECK	A,H	
403	ALCEA ROSEA	A,H	
404	ALCHEMILLA ALPINA	A,H	
405	ALCHEMILLA ARVENSIS	A,H	
406	ALCHEMILLA VULGARIS	A,H	
407	ALETRIS FARINOSA	A,H	
408	ALETRIS SPICATA	A,H	
409	ALEURITES MOLUCCANUS SEED OIL	E	Only for use in topical medicines for dermal application.
410	ALFADEX	A	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The maximum daily dose must provide no more than 6 g of alfadex.
411	ALGINATE-KONJAC-XANTHAN POLYSACCHARIDE COMPLEX	A	Only for use in oral medicines. Only for use when the dosage form is other than tablet. The maximum recommended daily dose must be no more than 13.5 g. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’ When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
412	ALGINIC ACID	E	
413	ALISMA ORIENTALE	A,H	
414	ALISMA PLANTAGO AQUATICA	A,H	
415	ALKANNA TINCTORIA	A,H	
416	ALKYL (C12-15) BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 21%.
417	ALLANTOIN	E	Only for use in topical medicines for dermal application.
418	ALLIARIA PETIOLATA	A,H	
419	ALLIUM CEPA	A,H	
420	ALLIUM FISTULOSUM	A,H	
421	ALLIUM HIEROCHUNTINUM	A,H	
422	ALLIUM MACROSTEMON	A,H	
423	ALLIUM ODORUM	A,H	
424	ALLIUM PORRUM	A,H	
425	ALLIUM SATIVUM	A,E,H	
426	ALLIUM SCHOENOPRASUM	A,H	
427	ALLIUM URSINUM	A,H	
428	ALLO-OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
429	ALLURA RED AC	E	Permitted for use as a colour for oral and topical use.
430	ALLURA RED AC ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
431	ALLYL ALPHA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
432	ALLYL AMYL GLYCOLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
433	ALLYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
434	ALLYL CYCLOHEXANEPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
435	ALLYL CYCLOHEXYLOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
436	ALLYL HEPTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
437	ALLYL HEPTYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
438	ALLYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
439	ALLYL ISOTHIOCYANATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
440	ALLYL PHENOXYACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
441	ALLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
442	ALMOND	E	
443	ALMOND OIL	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Almond oil. The concentration of Amygdalin in the medicine must be 0%. The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
444	ALNUS GLUTINOSA	A,H	
445	ALNUS INCANA SUBSP. RUGOSA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
446	ALOE BARBADENSIS	A,E	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe barbadensis. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect) When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			following warning statements on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
447	ALOE FEROX	A,E,H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			mandatory component of Aloe ferox. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'
448	ALOE PERRYI	A,H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe perryi. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'
449	ALOE VERA	A,E,H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloe vera. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
450	ALOES BARBADOS	A,H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes barbados. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'
451	ALOES CAPE	A,H	When the route of administration is oral or sublingual, Hydroxyanthracene derivatives calculated as anhydrous barbaloin is a mandatory component of Aloes cape. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'
452	ALOYSIA CITRODORA	A,H	
453	ALPHA CASOZEPINE ENRICHED HYDROLYSED MILK PROTEIN	A	Only for use in oral medicines. The medicine requires the following warning statements on the medicine label: - (BABY3) 'Not suitable for use in children under the age of twelve months - except on professional advice' - (COWMK) 'Derived from cow's milk.'
454	ALPHA-AMYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
455	ALPHA-AMYL CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
456	ALPHA-CEDRENE EPOXIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
457	ALPHA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
458	ALPHA-FARNESENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
459	ALPHA-FURFURYL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	OCTANOATE		flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
460	ALPHA-HEXYLCINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
461	ALPHA-IONOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
462	ALPHA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
463	ALPHA-IRONE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
464	ALPHA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
465	ALPHA-METHYL ANISALACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
466	ALPHA-METHYL BENZYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
467	ALPHA-METHYL BUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
468	ALPHA-METHYL BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
469	ALPHA-METHYL CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
470	ALPHA-METHYL FURFURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
471	ALPHA-METHYL NAPHTHYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
472	ALPHA-METHYLCINNAMYL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ALCOHOL		fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
473	ALPHA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
474	ALPHA-PHELLANDRENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
475	ALPHA-PINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
476	ALPHA-SINENSAL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
477	ALPHA-TERPINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
478	ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
479	ALPHA LIPOIC ACID	A	
480	ALPINIA GALANGA	A,H	
481	ALPINIA HAINANENSIS	A,H	
482	ALPINIA OFFICINARUM	A,H	
483	ALPINIA OXYPHYLLA	A,H	
484	ALSIDIUM HELMINTHOCHORTON	A,H	Iodine is a mandatory component of Alsidium helminthochorton.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral and sublingual use.
485	ALSTONIA BOONEI	A,H	
486	ALSTONIA CONSTRICTA	H	Only for use as an active homoeopathic ingredient.
487	ALTERNANTHERA PHILOXEROIDES	A,H	
488	ALTERNARIA ALTERNATA	A,H	
489	ALTHAEA OFFICINALIS	A,E,H	
490	ALUM DODECAHYDRATE	A,E,H	
491	ALUMINIUM CHLOROHYDRATE	E	Only for use in topical medicines for dermal application.
492	ALUMINIUM CITRATE	E	Only for use in topical medicines for dermal application.
493	ALUMINIUM DISTEARATE	E	Only for use in topical medicines for dermal application.
494	ALUMINIUM	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HYDROXIDE		dermal application.
495	ALUMINIUM HYDROXIDE HYDRATE	E	Only for use in topical medicines for dermal application.
496	ALUMINIUM MAGNESIUM SILICATE	E	
497	ALUMINIUM MONOSTEARATE	E	Only for use in topical medicines for dermal application.
498	ALUMINIUM OXIDE	E,H	When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient, only for use in homoeopathic medicines.
499	ALUMINIUM SILICATE	E,H	Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application.
500	ALUMINIUM SODIUM SILICATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
501	ALUMINIUM STARCH	E	The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	OCTENYLSUCCINATE		must be no more than 7%.
502	ALUMINIUM STEARATE	E	Only for use in topical medicines for dermal application.
503	ALUMINIUM SULFATE HYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
504	AMARANTH	E	Permitted for use as a colour for oral and topical use.
505	AMARANTH ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use
506	AMARANTHUS HYBRIDUS	A,H	
507	AMARANTHUS RETROFLEXUS	A,H	
508	AMBERGRIS EXTRACT	E	
509	AMBRETTE SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
510	AMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
511	AMBRINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
512	AMBROSIA ARTEMISIIFOLIA	A,H	
513	AMBROSIA PSILOSTACHYA	A,H	
514	AMINOBENZOIC ACID	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
515	AMINOCAPROIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
516	AMINOPROPYL ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
517	AMMI VISNAGA	A,H	The concentration of equivalent dry Ammi visnaga in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
518	AMMONIA	E,H	Only for use as an active homoeopathic or excipient ingredient. When used as an excipient ingredient, the medicine is only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
519	AMMONIO METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
520	AMMONIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
521	AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	E	Only for use in topical medicines for dermal application.
522	AMMONIUM ACRYLOYLDIMETHYL TAURATE/STEARETH-8 METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
523	AMMONIUM ACRYLOYLDIMETHYL TAURATE/VP COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 5%.
524	AMMONIUM BICARBONATE	A,H	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
525	AMMONIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
526	AMMONIUM CARBONATE	E,H	Only for use as an active homoeopathic or excipient ingredient.
527	AMMONIUM CHLORIDE	A,E,H	Only for use as an active ingredient in homoeopathic medicines or as an uncompounded medicine substance packed for retail sale. When used as an uncompounded medicine substance the ingredient must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. If used as an excipient ingredient then the medicine is only for topical use for dermal application.
528	AMMONIUM GLYCYRRHIZINATE	E	
529	AMMONIUM IODIDE	H	Only for use an active ingredient in homoeopathic medicines.
530	AMMONIUM LACTATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
531	AMMONIUM LAURETH SULFATE	E	Only for use in topical medicines for dermal application.
532	AMMONIUM LAURYL SULFATE	E	Only for use in topical medicines for dermal application.
533	AMMONIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
534	AMMONIUM POLYACRYLOYLDIMETHYL TAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 3%.
535	AMMONIUM SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
536	AMOMUM AROMATICUM	A,H	
537	AMOMUM VILLOSUM	A,H	
538	AMORPHOPHALLUS KONJAC	A,H	Only for use when the dosage form is not tablet.
539	AMPELODESMOS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	MAURITANICUS		
540	AMPELOPSIS JAPONICA	A,H	
541	AMYL ACETATE	E	Only for use in topical medicines for dermal application.
542	AMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
543	AMYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
544	AMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
545	AMYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
546	AMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
547	AMYL CINNAMIC ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
548	AMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
549	AMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
550	AMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
551	AMYL OCTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
552	AMYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
553	AMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
554	AMYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
555	AMYL VALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
556	AMYL VINYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
557	AMYL VINYL CARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
558	AMYLASE	A	Amylase must be derived from Aspergillus oryzae, and comply with the relevant compositional guideline. When used in a divided preparation, the allowed unit is Alpha-amylase dextrinising unit or Thousand alpha-amylase dextrinising unit. When used as an undivided preparation, the allowed unit is Thousand alpha-amylase dextrinising

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			unit per gram or Dextrinising unit per gram.
559	AMYLCYCLOHEXYL ACETATE (MIXED ISOMERS)	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
560	AMYLOPECTIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
561	AMYRIS BALSAMIFERA	A,H	
562	AMYRIS OIL WEST INDIAN	A,E,H	
563	ANACARDIUM OCCIDENTALE	A,H	
564	ANACYCLUS PYRETHRUM	A,H	
565	ANACYSTIS NIDULANS FERMENT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0025%.
566	ANAESTHETIC ETHER	H	Only for use as an active homoeopathic ingredient.
567	ANAGALLIS ARVENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
568	ANAMIRTA COCCULUS	A,H	Picrotoxin is a mandatory component of Anamirta cocculus. The concentration of picrotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
569	ANANAS COMOSUS	A,E,H	
570	ANAPHALIS SINICA	A,H	
571	ANDROGRAPHIS PANICULATA	A,H	
572	ANEMARRHENA ASPHODELOIDES	A,E,H	
573	ANEMONE ALTAICA	A,H	
574	ANEMONE CHINENSIS	A,H	
575	ANEMONE HEPATICA	A,H	
576	ANEMONE PULSATILLA	A,H	
577	ANEMONE RADDEANA	A,H	
578	ANETHOLE	E	
579	ANETHOLEA ANISATA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
580	ANETHUM GRAVEOLENS	A,E,H	
581	ANGELICA ACUTILOBA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
582	ANGELICA ANOMALA	A,H	
583	ANGELICA ARCHANGELICA	A,E,H	
584	ANGELICA ATROPURPUREA	A,H	
585	ANGELICA DAHURICA	A,E,H	
586	ANGELICA DECURSIVA	A,H	
587	ANGELICA POLYMORPHA	A,E,H	
588	ANGELICA PUBESCENS	A,E,H	
589	ANGELICA ROOT DRY	A,H	
590	ANGELICA ROOT OIL	A,E,H	
591	ANGELICA SEED OIL	A,E,H	
592	ANGELICA STEM	E	
593	ANIBA ROSAEODORA	A,E,H	
594	ANISALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
595	ANISE ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
596	ANISE OIL	A,E,H	When the concentration of Anise oil in the preparation is more than 50% the nominal capacity of the container must be no more than 50 mL. When the concentration of Anise oil in the preparation is more than 50% and the nominal capacity of the container is 50 mL or less, a restricted flow insert must be fitted on the container. The medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children (or word to that effect)'
597	ANISEED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
598	ANISEED DRY	A,E,H	
599	ANISEED POWDER	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
600	ANISIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
601	ANISYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
602	ANISYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
603	ANISYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
604	ANISYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
605	ANNATTO	E	Permitted for use as a colour for oral and topical use.
606	ANOGEISSUS LATIFOLIA	A,E,H	
607	ANTENNARIA DIOICA	A,E,H	
608	ANTHOCYANINS	E	
609	ANTHOXANTHUM ODORATUM	A,H	
610	ANTHRISCUS CEREFOLIUM	A,H	
611	ANTHYLLIS VULNERARIA	A,H	
612	ANTIMONY POTASSIUM TARTRATE TRIHYDRATE	H	Only for use as an active homoeopathic ingredient.
613	ANTIMONY TRISULFIDE	H	Only for use as an active homoeopathic ingredient.
614	APIUM GRAVEOLENS	A,E,H	
615	APOCYNUM CANNABINUM	A,H	The concentration of equivalent dry Apocynum cannabinum in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
616	APOMORPHINE HYDROCHLORIDE	H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HEMIHYDRATE		homoeopathic ingredient.
617	APPLE	E	
618	APPLE CIDER VINEGAR	E	
619	APPLE ESSENCE NATURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
620	APPLE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
621	APPLE FIBRE	E	
622	APRICOT	E	
623	APRICOT KERNEL OIL PEG-6 ESTERS	E	Only for use as an excipient in topical medicines for dermal application.
624	AQUILARIA MALACCENSIS	A,H	
625	AQUILARIA SINENSIS	A,H	
626	AQUILEGIA VULGARIS	A,H	
627	ARACHIDONIC ACID	E	Only for use in topical medicines for dermal application.
628	ARACHIDYL ALCOHOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 1%.
629	ARACHIDYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.5%.
630	ARACHIDYL PROPIONATE	E	Only for use in topical medicines for dermal application.
631	ARACHIS HYPOGAEA	A,E,H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains [insert ingredient name]'.
632	ARACHIS OIL	A,E,H	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains [insert ingredient name]'.
633	ARALIA CORDATA	A,H	
634	ARALIA HISPIDA	A,H	
635	ARALIA NUDICAULIS	A,H	
636	ARALIA RACEMOSA	A,H	
637	ARCTIUM LAPPA	A,E,H	
638	ARCTIUM MINUS	A,H	
639	ARCTOSTAPHYLOS UVA-URSI	A,E,H	
640	ARDISIA JAPONICA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
641	ARECA CATECHU	A,H	Arecoline is a mandatory component of Areca catechu. The concentration of arecoline in the medicine must be no more than 10 mg/Kg or 10 mg/L or 0.001%.
642	ARGANIA SPINOSA KERNEL OIL	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 5% in the medicine.
643	ARGININE	A,E,H	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (ARGIN1) 'This medicine contains arginine and is intended to be applied to the skin only and not to the mucosa - vagina or rectum.'
644	ARGININE FERULATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
645	ARISAEMA ATRORUBENS	A,H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
646	ARISAEMA CONSANGUINEUM	A,H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
647	ARISAEMA JAPONICUM	A,H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
648	ARMORACIA RUSTICANA	A,E,H	Volatile oil components (of Armoracia rusticana) is a mandatory component of Armoracia rusticana. The maximum recommended daily dose must contain no more than 20 mg of volatile oil components (of Armoracia rusticana).
649	ARNEBIA EUCHROMA	A,H	
650	ARNICA FLOWER DRY	A,H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry flower of Arnica montana.
651	ARNICA MOLLIS	A,H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
652	ARNICA MONTANA	A,H	When for use other than topically on unbroken skin, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of arnica montana.
653	ARRHENATHERUM ELATIUS	A,H	
654	ARROWROOT	A,E,H	
655	ARSENIC TRIIODIDE	H	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			0.001%.
656	ARSENIC TRIOXIDE	H	Only for use as an active homoeopathic ingredient. The concentration of arsenic in the medicine must be no more than 0.001%.
657	ARTEMISIA ABROTANUM	A,H	Thujone is a mandatory component of Artemisia abrotanum. The concentration of thujone from Artemisia abrotanum in the medicine must be no more than 4%.
658	ARTEMISIA ABSINTHIUM	A,H	Thujone is a mandatory component of Artemisia absinthium. The concentration of thujone from Artemisia absinthium in the medicine must be no more than 4%.
659	ARTEMISIA ANNUA	A,H	Thujone is a mandatory component of Artemisia annua. The concentration of thujone from Artemisia annua in the medicine must be no more than 4%.
660	ARTEMISIA ARBORESCENS	A,H	Thujone is a mandatory component of Artemisia arborescens. The concentration of thujone from Artemisia arborescens in the medicine must be no more than 4%.
661	ARTEMISIA ARGYI	A,H	Thujone is a mandatory component of Artemisia argyi. The concentration of thujone from Artemisia argyi in the medicine must be no more than 4%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
662	ARTEMISIA DRACUNCULUS	A,E,H	Thujone is a mandatory component of Artemisia dracunculus. The concentration of thujone from Artemisia dracunculus in the medicine must be no more than 4%.
663	ARTEMISIA FRIGIDA	A,H	Thujone is a mandatory component of Artemisia frigida. The concentration of thujone from Artemisia frigida in the medicine must be no more than 4%.
664	ARTEMISIA HERBA-ALBA	A,H	Thujone is a mandatory component of Artemisia herba-alba. The concentration of thujone from Artemisia herba-alba in the medicine must be no more than 4%.
665	ARTEMISIA MARITIMA	A,H	Thujone is a mandatory component of Artemisia maritima. The concentration of thujone from Artemisia maritima in the medicine must be no more than 4%.
666	ARTEMISIA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
667	ARTEMISIA PALLENS	A,E,H	Thujone is a mandatory component of Artemisia pallens. The concentration of thujone from

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Artemisia pallens in the medicine must be no more than 4%.
668	ARTEMISIA TRIDENTATA	A,H	Thujone is a mandatory component of Artemisia tridentata. The concentration of thujone from Artemisia tridentata in the medicine must be no more than 4%.
669	ARTEMISIA VULGARIS	A,E,H	Thujone is a mandatory component of Artemisia vulgaris. The concentration of thujone from Artemisia vulgaris in the medicine must be no more than 4%.
670	ARTERY	H	Only for use as an active homoeopathic ingredient.
671	ARTHROSPIRA MAXIMA	A,H	
672	ARTHROSPIRA PLATENSIS	A,H	
673	ARUM MACULATUM	A,H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
674	ASAFOETIDA GUM	A,H	
675	ASAFOETIDA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
676	ASARUM EUROPAEUM	A,H	
677	ASARUM HETEROTROPOIDES	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
678	ASARUM OIL	E	
679	ASARUM SIEBOLDII	A,E,H	
680	ASCLEPIAS TUBEROSA	A,H	
681	ASCOPHYLLUM NODOSUM	A,E,H	Iodine is a mandatory component of Ascophyllum nodosum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
682	ASCORBIC ACID	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’
683	ASCORBYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
684	ASCORBYL METHYLSILANOL PECTINATE	E	Only for use in topical medicines for dermal application.
685	ASCORBYL PALMITATE	A,E	When used as an active ingredient for oral use, the maximum recommended daily dose must contain no more than 100mg of ascorbyl palmitate. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
686	ASCORBYL TOCOPHERYL MALEATE	E	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0575%.
687	ASPALATHUS LINEARIS	A,E,H	
688	ASPARAGINE	A,E	
689	ASPARAGOPSIS SULFATED GALACTANS	E	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0025%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
690	ASPARAGUS	E,H	Only for use as an active homoeopathic or excipient ingredient.
691	ASPARAGUS COCHINCHINENSIS	A,H	
692	ASPARAGUS OFFICINALIS	A,E,H	
693	ASPARAGUS RACEMOSUS	A,H	The plant part must be dried, peeled root, and water extracts or ethanol/water extracts (containing up to 45% ethanol) of the dried, peeled root.
694	ASPARTAME	E	When for oral use, the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this product contains phenylalanine (or words to that effect)' The medicine requires the following warning statement on the medicine label: - (ASPAR) 'Contains aspartame'
695	ASPARTIC ACID	A,E	
696	ASPERGILLUS ORYZAE	A,E,H	
697	ASTAXANTHIN ESTERS EXTRACTED FROM HAEMATOCOCCUS PLUVIALIS	A	Only for use in oral medicines. Astaxanthin (of Haematococcus pluvialis) is a mandatory component of astaxanthin esters extracted from Haematococcus pluvialis. The maximum daily dose must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			contain no more than 12mg of Astaxanthin (of Haematococcus pluvialis).
698	ASTER NOVI-BELGII	A,H	
699	ASTER TATARICUS	A,H	
700	ASTRAGALUS ADSURGENS	A,H	
701	ASTRAGALUS COMPLANATUS	A,H	
702	ASTRAGALUS EXCARPUS	A,H	
703	ASTRAGALUS GUMMIFER	A,E,H	
704	ASTRAGALUS LENTIGINOSUS	A,H	
705	ASTRAGALUS MEMBRANACEUS	A,E,H	
706	ASTRAGALUS PENDULIFLORUS	A,H	
707	ASTROCARYUM MURUMURU SEED TRIGLYCERIDES	E	Only for use as an ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.21%.
708	ATRACTYLODES JAPONICA	A,H	
709	ATRACTYLODES LANCEA	A,H	
710	ATRACTYLODES	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	MACROCEPHALA		
711	ATROPA BELLADONNA	A,H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Atropa belladonna. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
712	ATROPINE SULFATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
713	ATTALEA SPECIOSA	E	Only for use in topical medicines for dermal application.
714	AURA B-AURANTIOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
715	AUREOBASIDIUM PULLULANS	A,H	
716	AVENA FATUA	A,H	Gluten is a mandatory component of Avena fatua when the plant part is seed and the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
717	AVENA SATIVA	A,E,H	Gluten is a mandatory component of Avena sativa when the plant part is seed and the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
718	AVOCADO	E	
719	AVOCADO OIL	E	
720	AVOCADO OIL UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
721	AZADIRACHTA INDICA	A,H	The ingredient can only be derived from the plant part seed and must be cold pressed or debitterised oil. "Debitterised neem seed oil" means highly purified oil from the neem seed containing only fatty acids and glycerides of fatty acids. Cold pressed Azadirachta indica seed oil must be for topical use for dermal application only. When the concentration of cold pressed Azadirachta indica seed oil is more than 1%, a child resistant closure and restricted flow insert must be fitted to the container.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The medicine requires the following warning statements on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant (or words to that effect)' - (NTAKEN) 'Not to be taken (or words to that effect)' - (CHILD) 'Keep out of reach of children (or words to that effect)'
722	AZOVAN BLUE	E	Permitted for use as a colour for topical use.
723	AZULENE	E	Only for use in topical medicines for dermal application.

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
724	BACKHOUSIA CITRIODORA	A,E,H	The herbal substance must be derived from leaf oil only. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%. The medicine requires the following warning statements on the medicine label: - (IRRIT) 'If irritation develops - discontinue use' - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
725	BACOPA MONNIERI	A,H	
726	BALLOTA NIGRA	A,H	
727	BALM OF GILEAD BUD DRY	A,H	
728	BALM OF GILEAD BUD POWDER	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
729	BALSAM COPAIBA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
730	BAMBUSA BREVIFLORA	A,E,H	
731	BAMBUSA TEXTILIS	A,H	
732	BANANA	E	
733	BANANA DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
734	BAPHICACANTHUS CUSIA	A,H	
735	BAPTISIA CONFUSA	A,H	
736	BAPTISIA TINCTORIA	A,H	
737	BARBAREA VULGARIS	A,H	
738	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
739	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
740	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
741	BARLEY	E	Gluten is a mandatory component of Barley when the route of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
742	BARLEY BRAN	E	Gluten is a mandatory component of Barley bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
743	BARLEY GERM	E	Gluten is a mandatory component of Barley germ when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
744	BARLEY LEAF	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
745	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
746	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
747	BASIC RED 1	E	Only for use as a colour in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
748	BASIC VIOLET 11:1	E	Only for use as a colour in topical medicines for dermal application and not intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
749	BASIL OIL COMOROS	A,E,H	Methyl chavicol is a mandatory component of Basil oil Comoros. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			children' (or words to that effect).
750	BASIL OIL EUROPEAN	A,E,H	Methyl chavicol is a mandatory component of Basil oil European. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
751	BASSIA SCOPARIA	A,H	
752	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
753	BAY LEAF	E	
754	BAY OIL	A,E,H	When the concentration of Bay oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is no more than 15 mL, there must be a restricted flow insert fitted on the container. When the concentration of Bay oil in the medicine is more than 25% and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
755	BEESWAX ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
756	BEET RED	E	Permitted for use as a colour for oral and topical use.
757	BEETROOT	E,H	
758	BEGONIA FIMBRISTIPULA	A,H	
759	BEHENETH-10	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. Residual levels of ethylene oxide are

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			to be kept below the level of detection.
760	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
761	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
762	BEHENOYL STEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.4%.
763	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
764	BELLADONNA HERB DRY	A,H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb dry. The concentration of alkaloids calculated as hyoscyamine in the medicine and must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
765	BELLADONNA HERB POWDER	A,H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb powder. The concentration of alkaloids calculated as hyoscyamine in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropinei n the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
766	BELLADONNA HERB PREPARED	A,H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
767	BELLIS PERENNIS	A,H	
768	BEMOTRIZINOL	A	Only for use as an active ingredient in topical sunscreens for dermal application. The concentration in the medicine must be no more than 10%.
769	BENINCASA HISPIDA	A,E,H	
770	BENTONITE	E	
771	BENZALDEHYDE	E	
772	BENZALDEHYDE GLYCERYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
773	BENZALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and nasal sprays. The concentration in the medicine must be no more than 5%.
774	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application. The medicine requires the warning statement: - (BNZTHC) 'Contains Benzethonium chloride' (or words to that effect).
775	BENZOIC ACID	E,H	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) ‘Contains benzoates' (or words to this effect)’ if the medicine contains two or more benzoate sources or ‘Contains [insert the approved name of benzoate used] (or words to this effect)’ if product contains one benzoate source.
776	BENZOIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
777	BENZOIN SIAM	A,E,H	
778	BENZOIN SUMATRA	A,E,H	
779	BENZOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
780	BENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
781	BENZYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
782	BENZYL ALCOHOL	E	The medicine requires the warning statement: - (BNZALC) 'Contains benzyl alcohol [quantity]' (or words to that effect).
783	BENZYL BENZOATE	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application. Medicines containing benzoates require the warning statement: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.
784	BENZYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
785	BENZYL CINNAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
786	BENZYL DIMETHYL CARBINYL-N-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
787	BENZYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
788	BENZYL ISOAMYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
789	BENZYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
790	BENZYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
791	BENZYL LAURATE	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
792	BENZYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
793	BENZYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
794	BENZYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
795	BENZYLIDENE ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
796	BENZYLIDENE CAMPHOR SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the preparation must be no more than 6% (as acid).
797	BERBERIS AQUIFOLIUM	A,H	
798	BERBERIS ARISTATA	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
799	BERBERIS VULGARIS	A,E,H	
800	BERGAMOT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
801	BERGAMOT OIL BERGAPTEN-FREE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
802	BERGAMOT OIL COLDPRESSED	A,E,H	When for internal use oxedrine is a mandatory component of bergamot oil coldpressed. The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.4 per cent or less of bergamot oil coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
803	BERGAMOT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
804	BERTHOLLETIA EXCELSA	A,E,H	
805	BETA-CARYOPHYLLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
806	BETA-DAMASCENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
807	BETA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
808	BETA-HOMO CYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
809	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
810	BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
811	BETA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
812	BETA-METHYL NAPHTHYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
813	BETA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
814	BETA-NAPHTHOL ETHYLETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
815	BETA-NAPHTHOL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
816	BETA-NAPHTHYL ISOBUTYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
817	BETA-PINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
818	BETA-TOCOPHEROL	E	
819	BETA RAPA	A,E,H	
820	BETA VULGARIS	A,E,H	
821	BETA,4-DIMETHYLCYCLOHEX-3-ENE-1-PROPAN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
822	BETACAROTENE	A,E	
823	BETADEX	E	
824	BETAGLUCAN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
825	BETAINE	E	Only for use in topical medicines for dermal application.
826	BETAINE HYDROCHLORIDE	E	
827	BETULA LENTA	A,H	Methyl salicylate is a mandatory component of Betula lenta. Only for use in topical medicines for dermal application. The concentration of methyl salicylate in the medicine must be no more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5%, and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging but the delivery device must be engaged into the container in such a way that prevents it from being readily removed, direct suction through the delivery device results in delivery of no more than one dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish.
828	BETULA NIGRA	A,H	
829	BETULA PENDULA	A,E,H	Methyl salicylate is a mandatory component of Betula pendula. Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application. The concentration of methyl salicylate in the medicine must be no more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5%, and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging but the delivery device must be engaged into the container in such a way that prevents it from being readily removed, direct suction through the delivery device results in delivery of no more than one dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish.
830	BETULA PUBESCENS	A,E,H	
831	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
832	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-METHYL-8-(1-METHYLETHYL)-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 1%.
833	BIFIDOBACTERIUM ADOLESCENTIS	A	
834	BIFIDOBACTERIUM ANIMALIS	A	
835	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
836	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
837	BIFIDOBACTERIUM BIFIDUM	A	
838	BIFIDOBACTERIUM BREVE	A	
839	BIFIDOBACTERIUM INFANTIS	A	
840	BIFIDOBACTERIUM LACTIS	A	
841	BIFIDOBACTERIUM LONGUM	A	
842	BILBERRY	E	
843	BIOSACCHARIDE GUM-1	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
844	BIOTA ORIENTALIS	A,H	
845	BIOTIN	A,E	When used as an active ingredient and the route of administration is oral or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
846	BIRCH LEAF DRY	A,E,H	
847	BIRCH TAR OIL RECTIFIED	A,E,H	
848	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
849	BIS-ETHYLHEXYL HYDROXYDIMETHOX Y BENZYLMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
850	BIS-MACROGOL 900 METHYL ETHER DIMETHYL SILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2.5%.
851	BIS-PEG-12 DIMETHICONE BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
852	BIS-STEARYL	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ETHYLENEDIAMINE/NEOPENTYL GLYCOL/STEARYL HYDROGENATED DIMER DILINOLEATE COPOLYMER		dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
853	BISABOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
854	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
855	BITTER ALMOND OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The absence of amygdalin in the medicine must be declared.
856	BIXA ORELLANA	A,E,H	
857	BLACK BONED CHICKEN POWDER	A	
858	BLACK COHOSH DRY	A,H	The medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
859	BLACK COHOSH POWDER	A,H	The medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
860	BLACK CURRANT	E	
861	BLACK CURRANT ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
862	BLACK CURRANT FRESH	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
863	BLACK CURRANT SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
864	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
865	BLACK PEPPER OIL	A,E,H	
866	BLACK RASPBERRY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
867	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
868	BLACKBERRY	E	
869	BLACKBERRY OILS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
870	BLACKBERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
871	BLACKCURRANT	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ESTERS		with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
872	BLACKCURRANT JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
873	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			to that effect).
874	BLADDERWRACK DRY	A,H	Iodine is a mandatory component of Bladderwrack dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
875	BLADDERWRACK POWDER	A,H	Iodine is a mandatory component of Bladderwrack powder. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
876	BLAINVILLEA ACMELLA	A,E,H	When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
877	BLETILLA STRIATA	A,H	
878	BLUE FLAG RHIZOME DRY	A,H	
879	BLUE FLAG RHIZOME POWDER	A,H	
880	BLUEBERRY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
881	BLUEBERRY JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
882	BLUMEA LACERA	A,H	
883	BOEHMERIA NIVEA	A,H	
884	BOERHAVIA DIFFUSA	A,H	
885	BOERHAVIA REPENS	A,H	
886	BOGBEAN LEAF DRY	A,H	
887	BOGBEAN LEAF POWDER	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
888	BOIS DE ROSE OIL	A,E,H	
889	BOMBAX CEIBA	A,H	
890	BORAGO OFFICINALIS	A,E,H	Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of Borago officinalis.
891	BORAX	A,E,H	Boron is a mandatory component of Borax. The percentage of Boron from Borax should be calculated based on the molecular weight of Borax. The maximum recommended daily dose must provide no more than 6mg of Boron. In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
892	BORAX PENTAHYDRATE	A,E	Boron is a mandatory component of Borax Pentahydrate. The percentage of Boron from Borax pentahydrate should be calculated based on the molecular weight of Borax Pentahydrate. The maximum recommended daily dose must provide no more than 6mg of Boron from Borax pentahydrate. In preparations for dermal use, which are not for paediatric or antifungal use,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
893	BORIC ACID	A,H	Boron is a mandatory component of Boric acid. The percentage of Boron from Boric acid should be calculated based on the molecular weight of Boric acid The maximum recommended daily dose must provide no more than 6mg of Boron. In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35% The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
894	BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
895	BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
896	BORON NITRIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
897	BORONIA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
898	BORONIA MEGASTIGMA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
899	BOSWELLIA CARTERII	A,E,H	
900	BOSWELLIA SERRATA	A,E,H	
901	BOSWELLIA THURIFERA	A,H	
902	BOTRYTIS CINEREA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
903	BOVINE CALCIUM CHONDROITIN SULFATE	A	
904	BOVINE CHONDROITIN SULFATE	A	
905	BOVINE COLOSTRUM POWDER	A	The medicine requires the warning statement: - (BOVCOL) 'Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.'
906	BOVINE LACTOFERRIN	A	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk.'
907	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
908	BOVINE SODIUM CHONDROITIN SULFATE	A	
909	BOVINE WHEY IG-RICH FRACTION	A	Only for use in oral medicines. The medicine requires the following warning statements on the medicine label: - (COWMK) 'Derived from cows milk' - (BABY3) 'Not suitable for use in

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			children under the age of 12 months - except on the advice of a health professional)'.
910	BRANDY	E	
911	BRASSICA CHINENSIS	A,H	Allyl isothiocyanate is a mandatory component of Brassica chinensis when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
912	BRASSICA JUNCEA	A,H	Allyl isothiocyanate is a mandatory component of Brassica juncea when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
913	BRASSICA NAPUS	A,E,H	Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
914	BRASSICA NIGRA	A,H	Allyl isothiocyanate is a mandatory component of Brassica nigra when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
915	BRASSICA OLERACEA VAR. BOTRYTIS	A,E,H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the plant part is seed. The maximum recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dose must not provide more than 20 mg of allyl isothiocyanate.
916	BRASSICA OLERACEA VAR. CAPITATA	A,E,H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. capitata when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
917	BRASSICA OLERACEA VAR. GEMMIFERA	A,H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. gemmifera when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
918	BRASSICA OLERACEA VAR. ITALICA	A,H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
919	BRASSICA OLERACEA VAR. VIRIDIS	A,H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. viridis when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
920	BRASSICA PEKINENSIS	A,H	Allyl isothiocyanate is a mandatory component of Brassica pekinensis when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
921	BRASSICA RAPA	A,E,H	Allyl isothiocyanate is a mandatory component of Brassica rapa when the plant part is seed. The maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
922	BRAZIL NUT	E	
923	BRILLIANT BLACK BN	E	Permitted for use as a colour for oral and topical use.
924	BRILLIANT BLUE FCF	E	Permitted for use as a colour for oral and topical use.
925	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
926	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use as a colour for oral and topical use.
927	BRILLIANT SCARLET 4R	E	Permitted for use as a colour for oral and topical use.
928	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
929	BRIZA MEDIA	A,H	
930	BROCCOLI	E	
931	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple (Ananas comosus). If used in a divided preparation, the allowed units are papain units and million papain units. If used in an undivided preparation, the allowed units are million papain units per gram.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
932	BROMINE	H	Only for use as an active homoeopathic ingredient. The concentration of bromine in the preparation must be no more than 14mg/Kg or 14mg/L or 0.0014% for oral and sublingual use.
933	BROMOSTYROL	E	Not for use in infants Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
934	BROMUS CATHARTICUS	A,H	
935	BROMUS INERMIS	A,H	
936	BROMUS RAMOSUS SUBSP. RAMOSUS	A,H	
937	BRONOPOL	E	Only for use as an excipient in topical medicines for dermal application. The medicine requires the warning statement: - (BRONOP) 'Contains bronopol [quantity]' (or words to that effect).
938	BROUSSONETIA PAPYRIFERA	A,H	
939	BROWN FK	E	Permitted for use as a colour for topical use.
940	BRUNFELSIA UNIFLORA	A,H	The maximum daily dose must be no more than the equivalent of 1mg of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dry herbal material.
941	BRUSSEL SPROUT	E	
942	BRYONIA ALBA	A,H	
943	BRYONIA DIOICA	A,H	
944	BUCHU LEAF DRY	A,H	
945	BUCHU LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
946	BUCHU LEAF POWDER	A,E,H	
947	BUCKWHEAT	E,H	Only for use as an active homoeopathic or excipient ingredient.
948	BUDDLEJA OFFICINALIS	A,H	
949	BULNESIA SARMIENTI	A,E,H	
950	BUNIAS ORIENTALIS	A,H	
951	BUPLEURUM FALCATUM	A,H	
952	BURDOCK LEAF DRY	A,H	
953	BURDOCK LEAF POWDER	A,H	
954	BURDOCK ROOT DRY	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
955	BURDOCK ROOT POWDER	A,H	
956	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
957	BUTAN-1-OL	E	The residual solvent limit for Butan-1-ol is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
958	BUTANE	E	Only for use as an excipient propellant ingredient.
959	BUTOXYETHANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
960	BUTTER	E	
961	BUTTER ACIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
962	BUTTER ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
963	BUTTER STARTER	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	DISTILLATE		with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
964	BUTYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
965	BUTYL ACETATE	E	The residual solvent limit for Butyl acetate is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
966	BUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
967	BUTYL BUTYRYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
968	BUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
969	BUTYL ESTER OF PVM/MA COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
970	BUTYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
971	BUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
972	BUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
973	BUTYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
974	BUTYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
975	BUTYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
976	BUTYL METHOXYDIBENZOYL METHANE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in preparation must be no more than 5%.
977	BUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
978	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
979	BUTYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
980	BUTYLATED HYDROXYANISOLE	E	The medicine requires the warning statement: - (BHANIS) 'Contains butylated hydroxyanisole' (or words to that effect).
981	BUTYLATED HYDROXYTOLUENE	E	
982	BUTYLENE GLYCOL DICAPRYLATE/DICAP	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	RATE		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
983	BUTYLIDENE PHTHALIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
984	BUTYLOCTYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
985	BUTYLPHENYL METHYLPROPIONAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
986	BUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
987	BUTYRIC ACID	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
988	C1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.012%.
989	C10-12 ALKANE/CYCLOALKANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
990	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.
991	C11-14-ISO-ALCOHOL C-13 RICH	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
992	C12-13 PARETH-23	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
993	C12-15 ALKYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.
994	C12-15 ALKYL OCTANOATE	E	Only for use in topical medicines for dermal application.
995	C12-20 ACID PEG-8 ESTER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
996	C12-20 ALKYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.75%.
997	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
998	C14-22 ALCOHOLS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in the eye. The concentration in the medicine must be no more than 2.55%.
999	C15-19 ALKANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
1000	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1001	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1002	C2-OCTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1003	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1004	C20-40 ALKYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1005	C20-40 PARETH-24	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 0.25%.
1006	C20-40 PARETH-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1007	C30-45 ALKYL CETEARYL DIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1008	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1009	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1010	C9-15 ALKYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.12%
1011	CABBAGE	E	
1012	CABREUVA OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1013	CADE OIL	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1014	CAESALPINIA SAPPAN	A,H	
1015	CAFFEINE	A,E	When used as an excipient, only for use in topical medicines for dermal application. Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and contains no more than 100 mg of caffeine per maximum daily dose. Medicines for oral use containing caffeine as an active ingredient require the following warning statement on the medicine label: - (ADULT) 'Adults only' (or words to that effect). When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			quantity per dosage unit or per mL or per gram of product]'.
1016	CAJUPUT OIL	A,E,H	Cineole is a mandatory component of Cajuput oil. When the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container. When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container. When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the medicine must have the restricted flow insert fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'.
1017	CALAMINE	A,E	Only for use as an active or excipient ingredient for dermal application. When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
1018	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1019	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1020	CALCIUM ALGINATE	E	
1021	CALCIUM AMINO ACID CHELATE	A,H	May only be used as a source of calcium. Calcium is a mandatory component of calcium amino acid chelate. The concentration of calcium in the calcium amino acid chealte must be no more than 25% w/w. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) ‘Source of calcium. May assist in the prevention and/or treatment of osteoporosis’ - (OSPOR2) ‘Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis’ - (CALC1) ‘Source of calcium. Women's calcium requirements are increased after menopause’ - (CALC2) ‘Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1022	CALCIUM ASCORBATE	A,E,H	The percentage of calcium from Calcium ascorbate should be calculated based on the molecular weight of calcium ascorbate. The percentage of ascorbic acid from calcium ascorbate should be calculated based on the molecular weight of calcium ascorbate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium Women's calcium requirements are

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1023	CALCIUM ASCORBATE DIHYDRATE	A,E,H	The percentage of ascorbic acid from Calcium ascorbate dihydrate should be calculated based on the molecular weight of Calcium ascorbate dihydrate. The percentage of calcium from Calcium ascorbate dihydrate should be calculated based on the molecular weight of Calcium ascorbate dihydrate. The following indications are only permitted when the medicine is for oral and sublingual use: (OSPOR1) 'Source of calcium. May assist in the prevention and/or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1024	CALCIUM ASPARTATE	A	Calcium is a mandatory component of Calcium aspartate and availability is restricted to use as a source of the relevant mineral only. The percentage of calcium from calcium aspartate should be calculated based on the molecular weight of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calcium aspartate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1025	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use as an active ingredient in oral medicines. Calcium is a mandatory component of Calcium aspartate hydrochloride dihydrate and availability is restricted to use as a source of the relevant mineral only. The percentage of calcium from calcium aspartate hydrochloride dihydrate should be calculated based on the molecular weight of calcium aspartate hydrochloride dihydrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1026	CALCIUM BEHENATE	E	Behenic acid is a mandatory component of Calcium behenate. When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 mg of Behenic acid.
1027	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A,H	The declared quantity of Calcium from Calcium beta-hydroxy-beta-methylbutryate must be no less than 13.9% and must be no more than 15.3% of the Calcium beta-hydroxy-beta-methylbutryate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.'
1028	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A,H	The declared quantity of Calcium from Calcium beta-hydroxy-beta-methylbutryate monohydrate must be no less than 13.07% and must be no more than 14.45% of the Calciumbeta-hydroxy-beta-methylbutryate monohydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.'
1029	CALCIUM CARBONATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium carbonate. The percentage of calcium from calcium carbonate should be calculated based on the molecular weight of calcium carbonate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1030	CALCIUM CASEINATE	E	
1031	CALCIUM CHLORIDE DIHYDRATE	E	
1032	CALCIUM CITRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			citrate. The percentage of calcium from calcium citrate should be calculated based on the molecular weight of calcium citrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead toosteoporosis in later life.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1033	CALCIUM CITRATE TETRAHYDRATE	A,E,H	If used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium citrate tetrahydrate. The amount of calcium in the active ingredient should be calculated based on the molecular weight of calcium citrate tetrahydrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1034	CALCIUM DIASPARTATE	A	Only for use as active ingredient in oral medicines. Calcium is a mandatory component of Calcium diaspartate and availability is restricted to use as a source of the relevant mineral only. The percentage of calcium from calcium diaspartate should be calculated based on the molecular weight of calcium diaspartate. The following indications are only permitted when the medicine is for oral and sublingual use:- (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause'- (CALC2)

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1035	CALCIUM FLUORIDE	H	The percentage of fluoride from Calcium fluoride should be calculated based on the molecular weight of Calcium fluoride.The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%.
1036	CALCIUM FOLINATE	A	Folinic acid is a mandatory component of calcium folinate. The maximum daily dose must provide no more than 500 micrograms of folinic acid. When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine provides not more than a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis.' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis.' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause.' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users.' OR 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults.' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone.' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral [may state the mineral] supplementation' is only

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			permitted for use when the medicine is for oral or sublingual use. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' OR 'Vitamin supplements should not replace a balanced diet.' When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the following statement must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'
1037	CALCIUM GLUCONATE MONOHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium gluconate monohydrate. The percentage of calcium from calcium gluconate monohydrate should be calculated based on the molecular weight of calcium gluconate. The following indications are only permitted when the medicine is for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1038	CALCIUM GLYCEROPHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			glycerophosphate. The percentage of calcium from calcium glycerophosphate should be calculated based on the molecular weight of calcium glycerophosphate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1039	CALCIUM GLYCINATE	A	Only for use as active ingredient in oral medicines. Calcium is a mandatory component of Calcium glycinate and availability is restricted to use as a source of the relevant mineral only. Based on molecular weights the declared quantity of Calcium from Calcium glycinate must be no less than 20.24% and no more than 22.37% of the Calcium glycinate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1040	CALCIUM GLYCINATE DIHYDRATE	A	Calcium is a mandatory component of Calcium glycinate dihydrate and availability is restricted to use as a source of the relevant mineral only. Based on molecular weights the declared quantity of Calcium from Calcium glycinate dihydrate must be no less than 17% and must be no more than 18.8% of the Calcium glycinate dihydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1041	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.
1042	CALCIUM HYDROGEN PHOSPHATE	A,E,H	Calcium is a mandatory component of calcium hydrogen phosphate. If used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			hydrogen phosphate. The percentage of calcium from calcium hydrogen phosphate should be calculated based on the molecular weight of calcium hydrogen phosphate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1043	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium hydrogen phosphate dihydrate. The percentage of calcium from calcium hydrogen phosphate dihydrate should be calculated based on the molecular weight of calcium hydrogen phosphate dihydrate. The following indications are only permitted when the medicine is for oral and sublingual use: (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1044	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium hydrogen phosphate monohydrate. The percentage of calcium from Calcium Hydrogen Phosphate Monohydrate should be calculated based on the molecular weight of Calcium Hydrogen Phosphate Monohydrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1045	CALCIUM HYDROXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium hydroxide. The percentage of calcium from calcium hydroxide should be calculated based on the molecular weight of calcium hydroxide. When used as a standard active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Pharmacopoeia, as in force or existing from time to time. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
1046	CALCIUM HYDROXYCITRATE	A,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium hydroxycitrate. The percentage of calcium from calcium hydroxycitrate should be calculated based on the molecular weight of Calcium hydroxycitrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) ‘Source of calcium. May assist in the prevention and/or treatment of osteoporosis’ - (OSPOR2) ‘Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis’ - (CALC1) ‘Source of calcium. Women's calcium requirements are increased after menopause’ - (CALC2) ‘Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults’ - (CALC3) ‘Source of calcium. Adequate dietary calcium in our youth and throughout life is required to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1047	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1048	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1049	CALCIUM KETOGLUCONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration must be no more than 1%
1050	CALCIUM L-THREONATE	A	Only for oral use. Calcium is a mandatory component of Calcium L-threonate. The percentage of calcium from calcium L-threonate should be calculated based on the molecular weight of calcium L-threonate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1051	CALCIUM LACTATE	A,E,H	If used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium lactate. The percentage of calcium from calcium lactate should be calculated based on the molecular weight of calcium lactate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1052	CALCIUM LACTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	GLUCONATE		supplementation, calcium is a mandatory component of Calcium lactate gluconate. The percentage of calcium from Calcium lactate gluconate should be calculated based on the molecular weight of Calcium lactate gluconate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1053	CALCIUM LACTATE PENTAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium lactate pentahydrate. The percentage of calcium from Calcium Lactate Pentahydrate should be calculated based on the molecular weight of Calcium Lactate Pentahydrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1054	CALCIUM LACTATE TRIHYDRATE	A,E,H	If used as an active ingredient and the preparation is intended as a mineral supplementation, calcium is a mandatory component of Calcium lactate trihydrate. The percentage of calcium from Calcium Lactate Trihydrate should be calculated based on the molecular weight of Calcium Lactate Trihydrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1055	CALCIUM LYSINATE	A	Only for use as active ingredient in oral medicines. Calcium is a mandatory component of Calcium lysinate and availability is restricted to use as a source of the relevant mineral only. The percentage of calcium from Calcium Lysinate should be calculated based on the molecular weight of Calcium Lysinate. The following indications are only permitted when the medicine is for oral and sublingual use:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1056	CALCIUM METHIONINATE	A	Only for use as active ingredient in oral medicines. Calcium is a mandatory component of Calcium methioninate and availability is restricted to use as a source of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			relevant mineral only. Based on molecular weights the declared quantity of Calcium from Calcium methioninate must be no less than 11.32% and must be no more than 12.51% of the Calcium methioninate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation.' is only permitted for use when the medicine is for oral or sublingual use.
1057	CALCIUM OROTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium orotate. The percentage of calcium from Calcium Orotate should be calculated based on the molecular weight of Calcium Orotate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1058	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1059	CALCIUM PANTOTHENATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium pantothenate. The percentage of calcium from Calcium Pantothenate should be calculated based on the molecular weight of Calcium Pantothenate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use. The following indications are only permitted when the medicine is for oral and sublingual use:
1060	CALCIUM PHOSPHATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, calcium is mandatory component of Calcium phosphate. The percentage of calcium from Calcium Phosphate should be calculated based on the molecular

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			weight of Calcium Phosphate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1061	CALCIUM PYRUVATE	A	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of Calcium pyruvate. The percentage of calcium from calcium pyruvate should be calculated based on the molecular weight of calcium pyruvate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1062	CALCIUM SACCHARATE	E	
1063	CALCIUM SILICATE	E	
1064	CALCIUM SODIUM CASEINATE	A,H	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk'.
1065	CALCIUM SODIUM LACTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium sodium lactate. The percentage of calcium from calcium sodium lactate should be calculated based on the molecular weight of calcium sodium lactate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1066	CALCIUM STEARATE	E	
1067	CALCIUM SUCCINATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium succinate. The percentage of calcium from calcium succinate should be calculated based on the molecular weight of calcium succinate. The following indications are only

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1068	CALCIUM SULFATE	A,E,H	If used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			mandatory component of calcium sulfate. The amount of calcium in the active ingredient should be calculated based on the molecular weight of calcium sulfate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation.' is only permitted for use when the medicine is for oral or sublingual use.
1069	CALCIUM SULFATE DIHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of calcium sulfate dihydrate. The percentage of calcium from calcium sulfate dihydrate should be calculated based on the molecular weight of calcium sulfate dihydrate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1070	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1071	CALCIUM THREONINATE	A	Only for use as an active ingredient. Calcium is a mandatory component of Calcium threoninate and availability is restricted to use as a source of the relevant mineral only. The percentage of calcium from Calcium Threonite should be calculated based on the molecular weight of Calcium Threonite. The following indications are only permitted when the medicine is for oral and sublingual use - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral or sublingual use.
1072	CALENDULA FLOWER DRY	A,E,H	
1073	CALENDULA FLOWER POWDER	A,H	
1074	CALENDULA OFFICINALIS	A,E,H	
1075	CALLERYA RETICULATA	A,H	
1076	CALLICARPA PEDUNCULATA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1077	CALLISTEMON CITRINUS	A,H	
1078	CALLISTEPHUS CHINENSIS	A,H	
1079	CALLITRIS INTRATROPICA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1080	CALLITRIS RHOMBOIDEA	A,H	
1081	CALLUNA VULGARIS	A,E,H	
1082	CALOCHORTUS TOLMIEI	A,H	
1083	CALTHA PALUSTRIS	A,H	
1084	CALUMBA ROOT DRY	A,H	
1085	CALUMBA ROOT POWDER	A,H	
1086	CALVATIA GIGANTEA	A,E,H	
1087	CALYCANTHUS FLORIDUS	A,H	
1088	CALYCANTHUS PRAECOX	A,H	
1089	CAMELLIA JAPONICA	A,H	
1090	CAMELLIA OLEIFERA	A,E,H	If Camellia oleifera (seed oil) is used as a solvent, it is restricted to topical or sunscreen preparations for dermal application only.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1091	CAMELLIA SINENSIS	A,E,H	Caffeine is a mandatory component of Camellia sinensis for oral use. Medicines for oral or sublingual administration that contain caffeine as a component of a herbal substance and that provide a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine require the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine require the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product].' Polyphenols calculated as gallic acid (of Camellia sinensis) is only permitted for use as a component when the plant part is leaf.
1092	CAMPHENE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
1093	CAMPHOR	E,H	In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
1094	CAMPHOR BENZALKONIUM METHOSULFATE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the preparation must be no more than 6%.
1095	CAMPHOR OIL BROWN	A,H	Camphor, cineole and safrole are mandatory components of Camphor oil brown. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have the restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.
1096	CAMPHOR OIL WHITE	A,E,H	Camphor and safrole are mandatory components of camphor oil white. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (NTAKEN) 'Not to be taken'. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.
1097	CAMPSIS GRANDIFLORA	A,H	
1098	CANADA BALSAM	A,H	
1099	CANANGA ODORATA	A,E,H	
1100	CANANGA OIL	A,E,H	
1101	CANARIUM INDICUM	A,H	The plant part must be seed and the plant preparation is oil. The medicine requires the following warning statement on the medicine label: - (DERIVED) 'This product contains material derived from nuts' (or words to that effect).
1102	CANARIUM LUZONICUM	A,H	
1103	CANDELILLA WAX	A,E,H	
1104	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1105	CANDIDA UTILIS	A,H	
1106	CANINE MILK	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1107	CANOLA OIL	A,E,H	Allyl isothiocyanate is a mandatory component of Canola oil. The maximum recommended daily dose must not provide more than 20 mg of Allyl isothiocyanate.
1108	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1109	CANTHAXANTHIN	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1110	CAPRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1111	CAPROIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1112	CAPRYLIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1113	CAPRYLIC/CAPRIC GLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1114	CAPRYLIC/CAPRIC/ISO STEARIC/ADIPIC TRIGLYCERIDE	E	
1115	CAPRYLIC/CAPRIC/MY RISTIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is not to exceed 3%
1116	CAPRYLIC/CAPRIC/ST EARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1117	CAPRYLOYL GLYCINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2%
1118	CAPRYLOYL	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	SALICYLIC ACID		dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must not be more than 0.3%.
1119	CAPRYLYL GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%
1120	CAPRYLYL METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1121	CAPSELLA BURSA-PASTORIS	A,H	
1122	CAPSICUM	E,H	Only for use as an active homoeopathic or excipient ingredient.
1123	CAPSICUM ANNUUM	A,E,H	
1124	CAPSICUM DRY	A,E,H	
1125	CAPSICUM FRUIT OLEORESIN	A,E	
1126	CAPSICUM FRUTESCENS	A,E,H	
1127	CAPSICUM POWDER	A,E,H	
1128	CARALLUMA ADSCENDENS VAR.	A	The plant part must be herb and the plant preparation must be a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	FIMBRIATA		hydroethanolic extract.
1129	CARAMEL	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1130	CARAPICHEA IPECACUANHA	A,H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must be no more than 0.2%. Except when used in a medicine containing only homoeopathic preparations, a child resistant closure must be fitted onto the container.
1131	CARAWAY DRY	A,H	
1132	CARAWAY OIL	A,E,H	
1133	CARAWAY POWDER	A,H	
1134	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1135	CARBOMER 2001	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.
1136	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1137	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1138	CARBOMER 940	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1139	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1140	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1141	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1142	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.
1143	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1144	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1145	CARBOMER U-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1146	CARBON	E,H	Only for use as an active homoeopathic or excipient ingredient.
1147	CARBON BLACK	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1148	CARBON DIOXIDE	E	
1149	CARDAMOM FRUIT DRY	A,H	
1150	CARDAMOM FRUIT POWDER	A,E,H	
1151	CARDAMOM OIL	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1152	CARDIOSPERMUM HALICACABUM	A,H	
1153	CARICA PAPAYA	A,E,H	
1154	CARLINA ACAULIS	A,H	
1155	CARMELLOSE	E	
1156	CARMELLOSE CALCIUM	E	
1157	CARMELLOSE SODIUM	E	
1158	CARMINE	E	Permitted for use as a colour for oral and topical use.
1159	CARMOISINE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1160	CARMOISINE ALUMINIUM LAKE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1161	CARNAUBA WAX	A,E,H	
1162	CARNOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1163	CAROB BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1164	CAROB GUM	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1165	CAROB POD	E	
1166	CAROTENES	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1167	CARPINUS BETULUS	A,H	
1168	CARPINUS CORDATA	A,H	
1169	CARRAGEENAN	E	
1170	CARROT	E	
1171	CARROT SEED OIL	A,E,H	
1172	CARTHAMUS TINCTORIUS	A,E,H	Carthamus tinctorius (sunflower oil) when used as a solvent is restricted to topical or sunscreen preparations for dermal application only. If for oral use, the medicine requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).
1173	CARUM CARVI	A,H	
1174	CARVACROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1175	CARVACRYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 1%.
1176	CARVEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1177	CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1178	CARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1179	CARYA ILLINOINENSIS	A,H	
1180	CARYA OVATA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1181	CARYOPHYLLENE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1182	CASCARA DRY	A,H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of Cascara dry when the route of administration is oral. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) ‘If symptoms persist consult your healthcare practitioner' (or words to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1183	CASCARA POWDER	A,H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of Cascara powder when the route of administration is oral administration. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) ‘If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) ‘Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
1184	CASCARILLA OIL	A,H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1185	CASEIN	E	
1186	CASHEW NUT	E	
1187	CASSIA ALATA LEAF EXTRACT	E	Only for use as an excipient ingredient in sunscreens for dermal application and not to be intended for use in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			eye. The extraction ratio of the Cassia alata can only be 1:3 in 62.5% glycerine:water. The concentration in the medicine must be no more than 0.0275%.
1188	CASSIA CINNAMON BARK DRY	A,H	When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of coumarin.
1189	CASSIA CINNAMON BARK POWDER	A,H	When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of coumarin.
1190	CASSIA FISTULA	A,H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Cassia fistula when the route of administration is oral. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect)

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
1191	CASSIA OCCIDENTALIS	A,H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Cassia occidentalis when the route of administration is oral administration. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (LAX1) 'Drink plenty of water [or words to that effect] When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'
1192	CASSIA OIL	A,E,H	The concentration of Cassia oil in the product must be no more than 2% unless the preparation is for dermal use as a rubefacient, in which case the concentration of cassia oil must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5%.
1193	CASSIE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1194	CASTANEA MOLLISSIMA	A,H	
1195	CASTANEA SATIVA	A,H	
1196	CASTOR OIL	A,E	
1197	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1198	CASUARINA EQUISITIFOLIA	A,H	
1199	CATALPA BIGNONIOIDES	A,H	
1200	CATALPA OVATA	A,H	
1201	CATECHU	A,H	
1202	CATHARANTHUS ROSEUS	A,H	Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Cantharanthus roseus. The concentration of vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1203	CAULIFLOWER	E	
1204	CAULOPHYLLUM THALICTROIDES	A,E,H	
1205	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1206	CEANOTHUS AMERICANUS	A,H	
1207	CEDAR LEAF OIL	A,E,H	
1208	CEDARWOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1209	CEDARWOOD OIL ATLAS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1210	CEDARWOOD OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1211	CEDARWOOD OIL VIRGINIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1212	CEDRENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1213	CEDRENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1214	CEDROL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1215	CEDRUS ATLANTICA	A,E,H	
1216	CEDRUS DEODARA	A,H	
1217	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1218	CEDRYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1219	CEDRYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1220	CELERY LEAF	E,H	
1221	CELERY SEED DRY	A,E,H	
1222	CELERY SEED OIL	A,E,H	
1223	CELERY SEED POWDER	A,H	
1224	CELLACEFATE	E	
1225	CELLULASE	A	Must be derived from Trichoderma longibrachiatum only. If used as an undivided preparation, the allowed unit is Cellulase unit per gram or Thousand cellulase unit per gram. If used as an divided preparation, the allowed unit is Thousand cellulase unit or cellulase unit.
1226	CELLULOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
1227	CELOSIA ARGENTEA	A,H	
1228	CELOSIA ARGENTEA L. VAR. CRISTATA	A,H	
1229	CENTAUREA CYANUS	A,E,H	
1230	CENTAURIUM ERYTHRAEA	A,H	
1231	CENTELLA ASIATICA	A,E,H	
1232	CENTELLA ASIATICA MERISTEM CELL CULTURE	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.05%.
1233	CENTIPEDA CUNNINGHAMII	A,E,H	
1234	CENTIPEDA MINIMA	A,H	
1235	CEPHALANOPSIS SEGETUM	A,H	
1236	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1237	CERAMIDE 2	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1238	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1239	CERATONIA SILIQUA	A,E,H	
1240	CERATOSTIGMA WILLMOTTIANUM	A,H	
1241	CERESIN	E	Only for use in topical medicines for dermal application.
1242	CESTRUM LATIFOLIUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The plant part must be leaf and must be a water extract. The concentration must be no more than 0.5%.
1243	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1244	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1245	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1246	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1247	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1248	CETEARETH-33	E	Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 0.2%. Residual levels of 1,4-dioxane oxide (and related substances) are to be kept below the level of detection.
1249	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1250	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1251	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1252	CETETH-10	E	Only for use in topical medicines for dermal application.
1253	CETETH-2	E	Only for use in topical medicines for dermal application.
1254	CETETH-24	E	Only for use in topical medicines for dermal application.
1255	CETETH-5	E	Only for use in topical medicines for dermal application.
1256	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1257	CETOMACROGOL 1000 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1258	CETOMACROGOL 500 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 2%.
1259	CETOSTEARYL ALCOHOL	E	
1260	CETOSTEARYL ALCOHOL/COCO-GLUCOSIDE COMPLEX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5.0 %
1261	CETRARIA ISLANDICA	A,H	
1262	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1263	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1264	CETYL-PG HYDROXYETHYL PALMITAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 8%.
1265	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1266	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1267	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1268	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1269	CETYL DIMETICONE/BIS-VINYLDIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CROSSPOLYMER		in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
1270	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1271	CETYL HYDROXYETHYLCELLULOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1272	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1273	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1274	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1275	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1276	CETYLPYRIDINIUM CHLORIDE	E	Only for use in topical medicines for dermal application. Medicines for topical use must include the name of any antimicrobial preservative in the goods.
1277	CHAENOMELES LAGENARIA	A,H	
1278	CHAENOMELES SPECIOSA	A,H	
1279	CHAETOMIUM INDICUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1280	CHALK	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
1281	CHAMAECYPARIS LAWSONIANA	A,H	
1282	CHAMAELIRIUM LUTEUM	A,H	
1283	CHAMAEMELUM NOBILE	A,E,H	
1284	CHAMOMILE FLOWER DRY	A,E,H	
1285	CHAMOMILE OIL ENGLISH	A,E,H	
1286	CHAMOMILE OIL GERMAN	A,E,H	
1287	CHANGIUM SMYRNIOIDES	A,H	
1288	CHEIRANTHUS CHEIRI	A,H	
1289	CHELIDONIUM MAJUS	A,E,H	When for oral or sublingual use, the medicine requires the following warning statement on the medicine label: - (CELAND) 'WARNING: Greater Celandine may harm the liver in some people. Use only under the supervision of a healthcare professional'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1290	CHELONE GLABRA	A,H	
1291	CHENOPODIUM ALBUM	A,H	
1292	CHENOPODIUM VULVARIA	A,H	
1293	CHERRY	E	
1294	CHERRY DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1295	CHESTNUT SWEET	E,H	
1296	CHILLI	E,H	
1297	CHIMAPHILA UMBELLATA	A,H	
1298	CHIONANTHUS VIRGINICA	A,H	
1299	CHLORELLA	E	Iodine is a mandatory component of Chlorella. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1300	CHLORELLA PYRENOIDOSA	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1301	CHLORELLA VULGARIS	A,E	Iodine is a mandatory component of Chlorella vulgaris. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1302	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1303	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1304	CHLOROACETAMIDE	E	Only for use in topical medicines for dermal application.
1305	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for localised effect. The concentration in the medicine must be no more than 0.5%. The medicine requires the following warning statement on the medicine label: - (CHLORB) 'Contains chlorbutol' (or words to that effect).
1306	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 3%. The medicine requires the following warning statement on the medicine label: - (CHLCRS) 'Contains chlorocresol [quantity]' (or words to that effect)
1307	CHLOROFORM	E	The residual solvent limit must be no more than 0.6 mg per recommended daily dose and the concentration in the medicine must be no more than 0.006%.
1308	CHLOROPHYLL	A,E	Only for use as a colour in oral and topical medicines.
1309	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1310	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1311	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1312	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1313	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1314	CHOCOLATE BROWN HT	E	Permitted for use as a colour for oral and topical use.
1315	CHOLESTEROL	E,H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1316	CHOLESTERYL	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HYDROXYSTEARATE		dermal application.
1317	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1318	CHOLESTERYL/BEHENYL/OCTYLDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
1319	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1320	CHOLINE BITARTRATE	A,E	
1321	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1322	CHONDRODENDRON TOMENTOSUM	A,H	The concentration of equivalent dry Chondrodendron tomentosum in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1323	CHONDRUS CRISPUS	A,E,H	Iodine is a mandatory component of Chondrus crispus. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			permitted when the medicine is for oral or sublingual use.
1324	CHONDRUS DRY	A,E,H	Iodine is a mandatory component of Chondrus dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1325	CHONDRUS EXTRACT	A,E,H	Iodine is a mandatory component of Chondrus extract. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1326	CHROMIC CHLORIDE HEXAHYDRATE	A,H	If used as an active ingredient in a preparation for mineral supplementation, chromium is a mandatory component of chromic

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			chloride hexahydrate. The amount of chromium in the active ingredient should be calculated based on the molecular weight of chromic chloride hexahydrate. The maximum recommended daily dose must provide 50 micrograms or less of chromium from organic sources (i.e.: chromium picolinate, chromium nicotinate and yeast - high chromium). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1327	CHROMIUM NICOTINATE	A	Chromium is a mandatory component of Chromium nicotinate. The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources. Chromium Nicotinate is considered to be an organic form of chromium. The indication 'For mineral (may state mineral) supplementation' is only permitted when the medicine is for oral and sublingual use.
1328	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate. The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources. Chromium picolinate is considered to be an organic form of chromium.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1329	CHRYSANTHEMUM BALSAMITA	A,H	
1330	CHRYSANTHEMUM INDICUM	A,H	
1331	CHRYSANTHEMUM LEUCANTHEMUM	A,H	
1332	CHRYSANTHEMUM MARSHALLII	A,H	
1333	CHRYSANTHEMUM SINENSE	A,H	
1334	CHRYSOPOGON ZIZANIOIDES	A,E,H	
1335	CHRYSOSPORIUM PRUINOSUM	A,H	
1336	CIBOTIUM BAROMETZ	A,H	
1337	CICHORIUM INTYBUS	A,E,H	
1338	CICUTA VIROSA	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1339	CINCHONA BARK DRY	A,H	Quinidine and quinine are mandatory components of Cinchona bark dry. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1340	CINCHONA BARK POWDER	A,H	Quinidine and quinine are mandatory components of Cinchona bark powder. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1341	CINCHONA OFFICINALIS	A,H	Quinidine and quinine are mandatory components of Cinchona officinalis. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1342	CINCHONA PUBESCENS	A,H	Quinidine and quinine are mandatory components of Cinchona pubescens. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1343	CINEOLE	E	In liquid preparations when the concentration of cineole in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1344	CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1345	CINNAMIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1346	CINNAMOMUM CAMPHORA	A,E,H	Camphor, cineole and safrole are mandatory components of Cinnamomum camphora. In solid and semi solid preparations, the concentration of camphor must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil preparations or distillates, the nominal capacity of the container must be no more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and - Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist. In essential oil preparations or distillates, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container. In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%. When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of coumarin.
1347	CINNAMOMUM CASSIA	A,E	Cassia oil is a mandatory component of Cinnamomum cassia if the plant preparation is an essential oil, distillate, fixed oil or infused oil. The concentration of Cassia oil in the medicine must be no more than 2%. When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of coumarin.
1348	CINNAMOMUM VERUM	A,E,H	When used as an active ingredient, coumarin is a mandatory component of Cinnamomum verum. Cinnamon bark oil is a mandatory component of Cinnamomum verum when the plant part is bark and the plant preparation is essential oil, distillate, fixed oil or infused oil. The concentration of cinnamon bark oil in the medicine must be no more than 2%. Cinnamon leaf oil is a mandatory component of Cinnamomum verum

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			when the plant part is leaf. When the concentration of cinnamon leaf oil in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but no more than 25millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the container must be fitted with a restricted flow insert. When used as an active ingredient: a) coumarin is a mandatory component of Cinnamomum verum; and b) the maximum daily dose of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must contain no more than 0.001% of coumarin.
1349	CINNAMON BARK OIL	A,E,H	The concentration of Cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% Coumarin.
1350	CINNAMON DRY	A,H	Cinnamon bark oil is a mandatory component of Cinnamon dry. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of Coumarin.
1351	CINNAMON LEAF OIL	A,E,H	When the concentration of cinnamon leaf oil in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) ‘Keep out of reach of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			children' (or words to that effect) - (NTAKEN) 'Not to be taken' When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL , the container must be fitted with a restricted flow insert and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of Coumarin.
1352	CINNAMON POWDER	A,E,H	Cinnamon bark oil is a mandatory component of Cinnamon powder. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% Coumarin.
1353	CINNAMYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1354	CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1355	CINNAMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1356	CINNAMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1357	CINNAMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1358	CINNAMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1359	CINNAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
1360	CINNAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1361	CINOXATE	A	Only for use as an active ingredient in sunscreens for dermal application only. The concentration of the ingredient must be no more than 6% and must not be used in topical products intended for use in the eye.
1362	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1363	CIS-3-HEXEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1364	CIS-3-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1365	CIS-3-HEXENYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1366	CIS-3-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1367	CIS-3-HEXENYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1368	CIS-3-HEXENYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1369	CIS-3-HEXENYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1370	CIS-3-HEXENYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1371	CIS-3-HEXENYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1372	CIS-3-HEXENYL	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ISOVALERATE		with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1373	CIS-3-HEXENYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1374	CIS-3-HEXENYL METHYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1375	CIS-3-HEXENYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1376	CIS-4-HEPTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1377	CIS-6-NONEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1378	CIS-6-NONENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1379	CIS-BETA-OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1380	CIS-HEXAHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1381	CIS-JASMONE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1382	CISTANCHE DESERTICOLA	A,H	
1383	CISTANCHE SALSA	A,H	
1384	CISTUS LADANIFERUS	A,E,H	
1385	CITRAL	E	
1386	CITRAL DIETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1387	CITRAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1388	CITRIC ACID	A,E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.
1389	CITRIC ACID	A,E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	DIHYDRATE		
1390	CITRIC ACID MONOHYDRATE	A,E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.
1391	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1392	CITROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1393	CITRON	E	
1394	CITRONELLA OIL	A,E,H	Medicines for topical use containing citronella oil require the following warning statement on the medicine label: - (CITRON) 'Contains citronella oil'.
1395	CITRONELLA TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1396	CITRONELLAL	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1397	CITRONELLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1398	CITRONELLOL	E	Only for use in topical medicines for dermal application.
1399	CITRONELLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1400	CITRONELLYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
1401	CITRONELLYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1402	CITRONELLYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1403	CITRONELLYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1404	CITRONELLYL OXYACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1405	CITRONELLYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1406	CITRONELLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1407	CITRONNOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1408	CITRULLUS COLOCYNTHIS	H	Only for use as an active homoeopathic ingredient. When for oral use, the concentration of Citrullus colocynthis must be more than 4X (i.e. 1X 2X 3X).
1409	CITRULLUS VULGARIS	A,H	
1410	CITRUS AURANTIFOLIA	A,E,H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus aurantifolia oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1411	CITRUS AURANTIUM	A,E,H	Oxedrine is a mandatory component of Citrus aurantium when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg. When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1412	CITRUS BIOFLAVONOIDS EXTRACT	A,E,H	
1413	CITRUS CHACHIENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1414	CITRUS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1415	CITRUS FIBRE	E	
1416	CITRUS LIMETTA	A,H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus limetta oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1417	CITRUS LIMON	A,E,H	Oxedrine is a mandatory component of Citrus limon when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			a) for internal use; or b) in preparations containing 0.05% or less of citrus limon oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1418	CITRUS MAXIMA	A,H	
1419	CITRUS MEDICA	A,E,H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus medica oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1420	CITRUS OIL DISTILLED	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1421	CITRUS RETICULATA	A,E,H	Oxedrine is a mandatory component of Citrus reticulata when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1422	CITRUS SINENSIS	A,E,H	Oxedrine is a mandatory component of Citrus sinensis when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1423	CITRUS SINENSIS PEEL MOLASSES EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1424	CITRUS UNSHIU	A,E,H	Oxedrine is a mandatory component of Citrus unshiu when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1425	CITRUS X PARADISI	A,E,H	
1426	CITRUS X WILSONII	A,H	
1427	CIVET	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1428	CIVET ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1429	CIVET SYNTHETIC	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1430	CIVETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1431	CLARY OIL	A,E,H	
1432	CLAVICEPS PURPUREA	A,H	The concentration of equivalent dry Claviceps purpurea must be no more than 10mg/Kg or 10mg/L or 0.001%.
1433	CLEMATIS ARMANDII	A,H	
1434	CLEMATIS CHINENSIS	A,E,H	
1435	CLEMATIS RECTA	A,H	
1436	CLEMATIS VITALBA	A,H	
1437	CLERODENDRUM TRICHOTOMUM	A,H	
1438	CLINOPODION POLYCEPHALUM	A,H	
1439	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A,H	
1440	CLIVER HERB DRY	A,H	
1441	CLIVER HERB	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	POWDER		
1442	CLOVE BUD OIL	A,E,H	When the concentration of Clove Bud Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Clove Bud Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' When the concentration of clove bud oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL , a restricted flow insert must be fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
1443	CLOVE DRY	A,E,H	
1444	CLOVE LEAF OIL	A,E,H	When the concentration of Clove Leaf Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			mL. When the concentration of Clove Leaf Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' When the concentration of clove leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
1445	CLOVE OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1446	CLOVE POWDER	A,E,H	
1447	CLOVE STEM OIL	A,E,H	When the concentration of Clove Stem Oil in the preparation is more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Clove Stem Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' When the concentration of Clove Stem oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL , a restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
1448	CLUPEA HARENGUS LIPID EXTRACT	A	Only for use in oral medicines. The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1449	CNICUS BENEDICTUS	A,H	
1450	CNICUS JAPONICUS	A,H	
1451	CNIDIUM MONNIERI	A,H	
1452	CNIDIUM OFFICINALE	A,H	
1453	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1454	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1455	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1456	COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%.
1457	COCAMIDOPROPYL BETAINE	E	Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be: a) no more than 1% in leave on medicines b) no more than 15% in wash on /wash off medicines c) 1.2% for buccal mucosa and dental medicines. Levels of impurities 3-dimethylaminopropylamine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(DMAPA) and amidoamine (dimethylaminopropylcocoamide; AA) must be controlled to below the level of detection.
1458	COCCOLOBIA UVIFERA	A,H	
1459	COCCULUS SARMENTOSUS	A,H	
1460	COCHINEAL	E,H	Only for use as an active homoeopathic or excipient ingredient. Permitted for use as a colour ingredient for oral and topical use.
1461	COCHLEARIA OFFICINALIS	A,H	
1462	COCHLIOBOLUS HETEROSTROPHUS	A,H	
1463	COCILLANA DRY	A,H	
1464	COCILLANA POWDER	A,H	
1465	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1466	COCO-CAPRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration is to be no more than 12.5% in the medicine.
1467	COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 0.025%
1468	COCO-OCTANOATE/DECANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
1469	COCOA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1470	COCOA POWDER	A,E,H	
1471	COCOGLYCERIDES	E	
1472	COCONUT	E	
1473	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1474	COCONUT OIL	A,E,H	
1475	COCOS NUCIFERA	A,E,H	
1476	COD-LIVER OIL	A,E	Vitamin A and colecalciferol are mandatory components of Cod-liver oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitaminD.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'Vitamin D helps calcium absorption (or words of like intent)' and 'A diet deficient in calcium can lead to osteoporosis in later life' are permitted only for oral use.
1477	CODONOPSIS LANCEOLATA	A,H	
1478	CODONOPSIS PILOSULA	A,H	
1479	CODONOPSIS TANGSHEN	A,H	
1480	COFFEA ARABICA	A,E,H	Caffeine is a mandatory component of Coffea arabica. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of caffeine.' b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1481	COFFEA CANEPHORA	A,E,H	Caffeine is a mandatory component of Coffea canephora. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1482	COFFEE	E,H	Caffeine is a mandatory component of coffee. When the route of administration is oral or sublingual and the medicine provides a maximum recommended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1483	COFFEE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1484	COFFEE SOLID EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1485	COGNAC OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
1486	COGNAC OIL GREEN	A,E,H	
1487	COGNAC OIL WHITE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1488	COIX LACHRYMA-JOBI	A,H	
1489	COLA ACUMINATA	A,E,H	Caffeine is a mandatory component of Cola acuminata. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the warning statement: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1490	COLA COTYLEDON DRY	A,H	Caffeine is a mandatory component of Cola cotyledon dry. When the route of administration is oral or sublingual and the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the warning statement: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1491	COLA COTYLEDON POWDER	A,H	Caffeine is a mandatory component of Cola cotyledon powder. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the warning statement: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1492	COLA NITIDA	A,E,H	Caffeine is a mandatory component of Cola nitida. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the warning statement: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1493	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient.
1494	COLECALCIFEROL	A,E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'vitamins can only be of assistance if the dietary intake is inadequate.' OR 'Vitamin supplements

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			should not replace a balanced diet.' The indication 'Vitamin D helps calcium absorption (or words to that intent) and a diet deficient in calcium can lead to osteoporosis in later life' is permitted only for oral use.
1495	COLEUS FORSKOHLII	A,E,H	
1496	COLLAGEN	E	
1497	COLLINSONIA CANADENSIS	A,H	
1498	COLLOIDAL ANHYDROUS SILICA	A,E,H	Only for use when the route of administration is other than inhalation.
1499	COLOPHONY	A,E,H	
1500	COMMIPHORA HABESSINICA	A,H	
1501	COMMIPHORA KATAF	A,H	
1502	COMMIPHORA MYRRHA	A,E,H	
1503	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1504	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1505	CONCENTRATED SQUID OMEGA-3 TRIGLYCERIDES	A	Only for oral use. 'Concentrated squid omega-3 triglycerides' must be obtained from species of the order Teuthida of the class Cephalopoda AND be in combination with other ingredients in the preparation AND be presented in a therapeutic dosage form for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			therapeutic use. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
1506	CONIFER GREEN NEEDLE COMPLEX	A	Only for topical and oral use. Must be made by petroleum ether extraction of needles of the conifer species Pinus sylvestris (Scotch Pine) and Picea abies (Norwegian Spruce).
1507	CONIFER PHYTOSTEROL COMPLEX	A	
1508	CONIOSELIUM UNIVITTATUM	A,H	
1509	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The concentration must be no more than exceed 12X homoeopathic dilution.
1510	CONVALLARIA MAJALIS	A,H	The concentration of equivalent dry Convallaria majalis in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1511	CONYZA CANADENSIS	A,H	
1512	COPAIBA OIL	A,E,H	
1513	COPAIFERA LANGSDORFFII	A,E,H	
1514	COPERNICIA CERIFERA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1515	COPOVIDONE	E	
1516	COPPER	H	Only for use as an active homoeopathic ingredient. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1517	COPPER (II) ASPARTATE	A,H	Copper is a mandatory component of copper (II) aspartate. The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of Copper (II) aspartate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral and sublingual use.
1518	COPPER (II) GLYCINATE	A,H	Copper is a mandatory component of copper (II) glycinate. The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dose must not contain more than 5mg of copper. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral and sublingual use.
1519	COPPER (II) LYSINATE	A,H	Copper is a mandatory component of copper (II) lysinate. The percentage of copper from copper (II) lysinate should be calculated based on the molecular weight of Copper (II) lysinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral and sublingual use.
1520	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1521	COPPER CHLOROPHYLL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1522	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1523	COPPER GLUCONATE	A,E	Copper is a mandatory component of copper gluconate. The percentage of copper from copper gluconate should be calculated based on the molecular weight of copper gluconate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is for oral and sublingual use.
1524	COPPER TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1525	COPTIS CHINENSIS	A,H	
1526	COPTIS JAPONICA	A,H	
1527	CORALLINA OFFICINALIS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is to be no more than 1%.
1528	CORDYCEPS SINENSIS	A,E,H	Must not contain material of animal origin such as insect larvae.
1529	CORIANDER DRY	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1530	CORIANDER OIL	A,E,H	
1531	CORIANDER POWDER	A,H	
1532	CORIANDRUM SATIVUM	A,E,H	
1533	CORN GLYCERIDES	E	
1534	CORN SILK DRY	A,H	
1535	CORN SILK POWDER	A,H	
1536	CORN SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1537	CORN SYRUP SOLIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1538	CORNUS FLORIDA	A,H	
1539	CORNUS OFFICINALIS	A,H	
1540	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1541	CORYDALIS AMBIGUA	A,E,H	
1542	CORYDALIS BUNGEANA	A,H	
1543	CORYDALIS CAVA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1544	CORYDALIS FABACEA	A,H	
1545	CORYDALIS FORMOSA	A,H	
1546	CORYDALIS TURTSCHANINOVII	A,H	
1547	CORYLUS AMERICANA	A,H	
1548	CORYLUS AVELLANA	A,H	
1549	CORYMBIA CITRIODORA	A,E,H	Cineole is a mandatory component of Corymbia citriodora. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must also have a child resistant closure.
1550	CORYMBIA FICIFOLIA	A,H	Cineole is a mandatory component of Corymbia ficifolia. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1551	COSMOS BIPINNATUS	A,H	
1552	COSTUS ROOT OIL	A,H	
1553	COSTUS SPICATUS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1554	COTTONSEED OIL	A,E,H	
1555	COUCH GRASS RHIZOME DRY	A,H	
1556	COUCH GRASS RHIZOME POWDER	A,H	
1557	COUMARIN	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
1558	CRANBERRY	E	
1559	CRATAEGUS CUNEATA	A,E,H	
1560	CRATAEGUS LAEVIGATA	A,E,H	
1561	CRATAEGUS MONOGYNA	A,E,H	
1562	CRATAEGUS PINNATIFIDA	A,E,H	
1563	CRATEVA NURVALA	A,E,H	
1564	CREATINE	A,E	The medicine requires the following warning statement on the medicine label: - (PROFES) 'Seek professional advice before long term use'.
1565	CREATINE MONOHYDRATE	A,E	The medicine requires the following warning statement on the medicine label: - (PROFES) 'Seek professional advice before long term use'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1566	CREATINE PHOSPHATE	A,E	The medicine requires the following warning statement on the medicine label: - (PROFES) 'Seek professional advice before long term use'.
1567	CREATININE	E	Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1568	CREOSOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1569	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1570	CRESOL	E	Only for use as a preservative in topical medicines. The concentration of phenols (including cresols and xylenols and any other homologue of phenol) boiling below 220 degrees centigrade must be no more than 3%. The medicine requires the following warning statement on the medicine label: - (CRESOL) 'Contains cresol' (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			words to that effect)
1571	CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1572	CRITHMUM MARITIMUM WHOLE PLANT EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00341%.
1573	CROCUS SATIVUS	A,H	
1574	CROSCARMELLOSE SODIUM	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1575	CROSPOVIDONE	E	
1576	CROTON CASCARILLA	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1577	CROTON ELUTERIA	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			material.
1578	CRYPTOMERIA JAPONICA	A,H	
1579	CUBEB OIL	A,H	
1580	CUBEBENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1581	CUCUMBER	E	
1582	CUCUMIS MELO	A,H	
1583	CUCUMIS SATIVUS	A,E,H	
1584	CUCURBITA MAXIMA	A,E,H	
1585	CUCURBITA MOSCHATA	A,H	
1586	CUCURBITA PEPO	A,E,H	
1587	CULLEN CORYLIFOLIUM	A,H	
1588	CUMIC ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1589	CUMIN OIL	A,E,H	
1590	CUMINALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1591	CUMINUM CYMINUM	A,H	
1592	CUMINYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1593	CUPRESSUS ARIZONICA	A,H	
1594	CUPRESSUS FUNEBRIS	A,E,H	
1595	CUPRESSUS MACROCARPA	A,H	
1596	CUPRESSUS SEMPERVIRENS	A,E,H	
1597	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1598	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1599	CUPRIC CITRATE	A,E,H	When for oral or sublingual use, copper is a mandatory component of Cupric citrate. The percentage of copper from cupric citrate should be calculated based on

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the molecular weight of cupric citrate. The medicine must not contain more than 750 micrograms of copper from Cupric citrate per the recommended daily dose or the medicine must not contain more than 1.86 milligrams of cupric citrate per the recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1600	CUPRIC CITRATE HEMIPENTAHYDRATE	A,E,H	When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate. The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate hemipenthydrate. The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1601	CUPRIC OXIDE	A,E,H	When for oral or sublingual use, copper is a mandatory component of Cupric oxide.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The percentage of copper from cupric oxide should be calculated based on the molecular weight of cupric oxide. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1602	CUPRIC SULFATE	A,E,H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate. The percentage of copper from cupric sulfate should be calculated based on the molecular weight of cupric sulfate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1603	CUPRIC SULFATE MONOHYDRATE	A,E,H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate. The percentage of copper from cupric

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.
1604	CUPRIC SULFATE PENTAHYDRATE	A,E,H	Where for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate. The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate. The percentage of cupric sulfate from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate. The indication'For mineral (may state

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1605	CURCULIGO ORCHIOIDES	A,H	
1606	CURCUMA AROMATICA	A,H	
1607	CURCUMA LONGA	A,E,H	
1608	CURCUMA XANTHORRHIZA	A,H	
1609	CURCUMA ZEDOARIA	A,H	
1610	CURCUMIN	A,E,H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1611	CUSCUTA EPITHYMUM	A,H	
1612	CUSCUTA EUROPAEA	A,H	
1613	CUSCUTA HYGROPHILAE	A,H	
1614	CUSCUTA RACEMOSA	A,H	
1615	CUSPARIA FEBRIFUGA	A,H	
1616	CYAMOPSIS TETRAGONOLOBA	A,E,H	
1617	CYANOCOBALAMIN	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The following indications are permitted for the medicine: - (VIT3) 'May assist in the management of dietary vitamin B12 deficiency.' - (VB121) 'Source of vitamin B12. Can assist in maintaining normal blood.' - (VB122) 'Source of vitamin B12. Can assist in maintaining normal blood. Blood tonic.'
1618	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1619	CYATHULA OFFICINALIS	A,H	
1620	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1621	CYCLAMEN PURPURASCENS	A,H	
1622	CYCLOHEXADECENONE-8	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1623	CYCLOHEXANE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1624	CYCLOHEXANE, 1-ETHENYL-1-METHYL-2-(1-METHYLETHENYL)-4-(1-METHYLETHYL)-, DIDEHYDRO DERIV.	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1625	CYCLOHEXANEETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1626	CYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1627	CYCLOHEXYL PHENETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 1%.
1628	CYCLOHEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1629	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1630	CYCLOPENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1631	CYDONIA OBLONGA	A,H	
1632	CYMBOPOGON FLEXUOSUS	A,E,H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1633	CYMBOPOGON MARTINI	A,H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1634	CYMBOPOGON NARDUS	A,H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1635	CYMBOPOGON SCHOENANTHUS	A,E,H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1636	CYNANCHUM ATRATUM	A,H	
1637	CYNANCHUM STAUNTONII	A,E,H	
1638	CYNARA SCOLYMUS	A,E,H	
1639	CYNODON DACTYLON	A,E,H	
1640	CYNOMORIUM SONGARICUM	A,H	
1641	CYPERUS LONGUS	A,H	
1642	CYPERUS ROTUNDUS	A,H	
1643	CYPRESS OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1644	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A,H	
1645	CYSTEINE	A	
1646	CYSTEINE HYDROCHLORIDE	A	
1647	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A,E	When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1648	CYSTINE	A	
1649	CYTISUS SCOPARIUS	A,H	Sparteine is a mandatory component of Cytisus scoparius. The concentration of Sparteine in the medicine must be no more than 0.001%.
1650	D-ALPHA-TOCOPHEROL	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
1651	D-ALPHA-TOCOPHERYL ACETATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
1652	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			balanced diet.'
1653	D-ALPHA-TOCOPHERYL PHOSPHATES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%.
1654	D-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1655	D-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1656	D-FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1657	D-LIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1658	D-PULEGONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The concentration of d-pulegone in the medicine must be no more than 4%.
1659	D-RIBOSE-L-CYSTEINE	A	Only for use in oral medicines. Cysteine is a mandatory component of D-Ribose-L-Cysteine. The medicine must provide no more than 450 mg of cysteine per maximum recommended daily dose.
1660	DACTYLIS GLOMERATA	A,H	
1661	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A,H	
1662	DAEMONOROPS DRACO	A,E,H	
1663	DAHLIA PINNATA	A,H	
1664	DALBERGIA ODORIFERA	A,H	
1665	DAMIANA LEAF	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	POWDER		
1666	DANDELION LEAF DRY	A,H	
1667	DANDELION LEAF POWDER	A,H	
1668	DANDELION ROOT DRY	A,H	
1669	DANDELION ROOT POWDER	A,H	
1670	DAPHNE GENKWA	A,H	
1671	DAPHNE MEZEREUM	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1672	DATE	E	
1673	DATURA STRAMONIUM	A,H	Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1674	DAUCUS CAROTA	A,E,H	
1675	DAVANA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1676	DEA-OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1677	DECAHYDRO-2,2,6,6,7,8,8-HEPTAMETHYL-2H-INDENO(4,5-B) FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1678	DECAHYDRO-BETA-NAPHTHYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1679	DECAHYDRO-BETA-NAPHTHYLFORMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
1680	DECAHYDROSPIRO(FURAN-2(3H),5'-(4,7)METHANO(5H)INDENE)	E	
1681	DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1682	DECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1683	DECANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1684	DECARBOXY CARNOISINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	DIHYDROCHLORIDE		in the eye. The concentration in the medicine must be no more than 0.05.
1685	DECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1686	DECYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1687	DECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1688	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1689	DECYL OLEATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1690	DECYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
1691	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1692	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (Cervus elaphus), elk/wapiti (Cervus canadensis), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.
1693	DEER VELVET	A	Medicines that contain 'deer velvet antler slice' as the therapeutically

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ANTLER SLICE		active ingredient are subject to the following conditions: a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (Cervus elaphus), elk/wapiti (Cervus canadensis), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.
1694	DEERTONGUE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1695	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (DACACD) 'Contains dehydroacetic acid [quantity]' (or words to that effect).
1696	DEHYDROMENTHOFUROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1697	DEHYDROXANTHAN GUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1698	DELPHINIUM STAPHISAGRIA	A,H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1699	DELTA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1700	DELTA-DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
1701	DELTA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1702	DELTA-NONALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1703	DELTA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1704	DELTA-TETRADECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
1705	DELTA-TOCOPHEROL	E	
1706	DELTA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1707	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1708	DENATONIUM BENZOATE	E	
1709	DENDROBIUM NOBILE	A,H	
1710	DESCURAINIA SOPHIA	A,H	
1711	DESMODIUM STYRACIFOLIUM	A,H	
1712	DESMODIUM TRIQUETUM	A,H	
1713	DEVIL'S CLAW TUBER DRY	A,H	
1714	DEVIL'S CLAW TUBER POWDER	A,H	
1715	DEXPANTHENOL	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
1716	DEXTRAN 20	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
1717	DEXTRAN 40	A,E	
1718	DEXTRATES	E	
1719	DEXTRIN	E	
1720	DEXTRIN PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1721	DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL	A	Only for use in oral medicines when in combination with other active or excipient ingredients. The ratio of docosahexaenoic acid (DHA) to eicosapentaenoic acid (EPA) must be 2:1.
1722	DI-C12-13 ALKYL MALATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 5%.
1723	DI-C12-15 ALKYL FUMARATE	E	Only for use in topical medicines forr dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1724	DI-N-PROPYL ISOCINCHOMERONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
1725	DI-PPG-3 MYRISTYL ETHER ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
1726	DIACETIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1727	DIACETYL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1728	DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1729	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.
1730	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1731	DIANTHUS SUPERBUS	A,H	
1732	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application. The medicine requires requires the following warning statement on the medicine label: - (DUREA) 'Contains diazolidinyl urea' (or words to that effect).
1733	DIBASIC POTASSIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate. The percentage of potassium from dibasic potassium phosphate should be calculated based on the molecular

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			weight of dibasic potassium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1734	DIBASIC SODIUM PHOSPHATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate. The percentage of Sodium from Dibasic sodium phosphate should be calculated based on the molecular weight of Dibasic sodium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1735	DIBASIC SODIUM PHOSPHATE DIHYDRATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate. The percentage of Sodium from Dibasic sodium phosphate dihydrate should be calculated based on the molecular weight of Dibasic sodium phosphate dihydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			permitted when the medicine is for oral or sublingual use.
1736	DIBASIC SODIUM PHOSPHATE DODECAHYDRATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dodecahydrate. The percentage of sodium from Dibasic sodium phosphate dodecahydrate should be calculated based on the molecular weight of Dibasic sodium phosphate dodecahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1737	DIBASIC SODIUM PHOSPHATE	A,E,H	When used as an active ingredient and the preparation is intended as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HEPTAHYDRATE		mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate. The amount of sodium in the active ingredient should be calculated based on the molecular weight of dibasic sodium phosphate heptahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1738	DIBASIC SODIUM PHOSPHATE MONOHYDRATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate. The percentage of Sodium from Dibasic sodium phosphate monohydrate should be calculated

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			based on the molecular weight of Dibasic sodium phosphate monohydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1739	DIBASIC TETRAHYDRATE MAGNESIUM CITRATE	A	Only for use in oral medicines. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of dibasic tetrahydrate magnesium citrate. The percentage of magnesium from dibasic tetrahydrate magnesium citrate should be calculated based on the molecular weight of dibasic tetrahydrate magnesium citrate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1740	DIBASIC TRIHYDRATE MAGNESIUM PHOSPHATE	A,E,H	Magnesium is a mandatory component of Dibasic trihydrate magnesium phosphate. The percentage of magnesium from dibasic trihydrate magnesium phosphate should be calculated based on the molecular weight of dibasic trihydrate magnesium phosphate.
1741	DIBASIC TRIHYDRATE POTASSIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic trihydrate potassium phosphate. The percentage of potassium from dibasic trihydrate potassium phosphate should be calculated based on the molecular weight of dibasic trihydrate potassium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1742	DIBENZYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1743	DIBUTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1744	DIBUTYL PHTHALATE	E	Only for use in topical medicines for dermal application.
1745	DIBUTYL SEBACATE	E	
1746	DIBUTYLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1747	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1748	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1749	DICAPRYLYL MALEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1750	DICETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1751	DICHLOROBENZYL ALCOHOL	E	
1752	DICHLOROMETHANE	E	The concentration in the medicine must be no more than 0.06%. The residual solvent limit for Dichloromethane is 6 mg per recommended daily dose.
1753	DICTAMNUS ALBUS	A,H	
1754	DICTAMNUS DESYCARPUS	A,H	
1755	DICYCLOHEXYL DISULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1756	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1757	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
1758	DIETHYL CITRACONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1759	DIETHYL MALONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1760	DIETHYL PHTHALATE	E	
1761	DIETHYLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1762	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1763	DIETHYLAMINOMETHYLCOUMARIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1764	DIETHYLDIMETHYL-2-CYCLOHEXENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1765	DIETHYLENE GLYCOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1766	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1767	DIETHYLHEXYL-2,6-NAPHTHALATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1768	DIETHYLHEXYL CARBONATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%.
1769	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1770	DIETHYLHEXYL SYRINGYLIDENEMAL	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ONATE		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1771	DIETHYLTOLUAMIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 20%. The medicine requires the following warning statement on the medicine label: - (DEET) 'WARNING: May be dangerous; particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.'
1772	DIGITALIS LEAF DRY	A,H	The concentration of Digitalis leaf dry in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1773	DIGITALIS LEAF POWDER	A,H	The concentration of Digitalis leaf powder in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1774	DIGITALIS PURPUREA	A,H	The concentration of equivalent dry Digitalis purpurea in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
1775	DIGLYCOL/CHDM/ISO PHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1776	DIHEXYL FUMARATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1777	DIHYDRO-ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1778	DIHYDRO-BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1779	DIHYDRO-ISOJASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1780	DIHYDRO JASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1781	DIHYDRO	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TERPINYLACETATE		with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1782	DIHYDROACTINIDIOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1783	DIHYDROAMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1784	DIHYDROCARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1785	DIHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1786	DIHYDROEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1787	DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1788	DIHYDROINDENYL-2,4-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1789	DIHYDROLINALOOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1790	DIHYDROMYRCENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
1791	DIHYDROMYRCENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1792	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1793	DIISOPROPYL ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
1794	DIISOPROPYL SEBACATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1795	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1796	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1797	DILL HERB OIL	A,E,H	
1798	DILL SEED OIL	A,E,H	
1799	DILL WEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
1800	DIMER DISTEARYLTRICARBONATE	E	Only for use in topical medicines for dermal application and not to be used in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
1801	DIMETHICONE 12500	E	
1802	DIMETHICONE 4000	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1803	DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1804	DIMETHICONE SILYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1805	DIMETHICONE/METHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 4%.
1806	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1807	DIMETHYL 3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1808	DIMETHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1809	DIMETHYL BENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1810	DIMETHYL BENZYL CARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1811	DIMETHYL BENZYL CARBINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1812	DIMETHYL BENZYL CARBINYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1813	DIMETHYL PHENYLETHYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1814	DIMETHYL PHTHALATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1815	DIMETHYL POLYSILOXANE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1816	DIMETHYL SUCCINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1817	DIMETHYL SULFATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1818	DIMETHYL SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1819	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1820	DIMETHYL SULFOXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1821	DIMETHYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1822	DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1823	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1824	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.
1825	DIMETICONE 1.5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1826	DIMETICONE 10	E	
1827	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1828	DIMETICONE 1000	E	
1829	DIMETICONE 1510	E	Permitted for use only in combination with other permitted ingredients as a printing ink.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
1830	DIMETICONE 2	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 2.5%.
1831	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1832	DIMETICONE 200	E	Only for use in topical medicines for dermal application.
1833	DIMETICONE 30	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration is the medicine must be no more than 4%.
1834	DIMETICONE 350	E	Only for use in topical and oral medicines. When used orally, the maximum daily dose must be no more than 7.5mg.
1835	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1836	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1837	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1838	DIMETICONE 50	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
1839	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1840	DIMETICONE 6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1841	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1842	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1843	DIMETICONE CROSSPOLYMER-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1844	DIMETICONE/PEG-10/15 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1845	DIMETICONOL	E	Only for use in topical medicines for dermal application.
1846	DIMETICONOL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in the eye. The concentration in the medicine must be no more than 2%.
1847	DIMOCARPUS LONGAN	A,H	
1848	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1849	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1850	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1851	DIOCTYL TEREPHTHALATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1852	DIOLAMINE C8-18 PERFLUOROALKYLETHYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.7%
1853	DIOLAMINE CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye.
1854	DIOSCOREA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	COLLETTII		
1855	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A,H	
1856	DIOSCOREA JAPONICA	A,H	
1857	DIOSCOREA OPPOSITIFOLIA	A,H	
1858	DIOSCOREA POLYSTACHYA	A,H	
1859	DIOSCOREA SEPTEMLOBA	A,H	
1860	DIOSCOREA VILLOSA	A,E,H	
1861	DIOSPYROS KAKI	A,E,H	
1862	DIOXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in a medicine must be no more than 3%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1863	DIPENTAERYTHRITYL HEXACAPRYLATE/HE	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	XACAPRATE		included in medicines intended for use on damaged skin. The concentration in the medicine must be no more than 0.5%.
1864	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TETRAISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1865	DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1866	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1867	DIPHENYL METHANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1868	DIPHENYL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
1869	DIPOTASSIUM GLYCYRRHIZATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
1870	DIPROPIONYL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1871	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1872	DIPROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.2%.
1873	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1874	DIPSACUS ASPER	A,H	
1875	DIPSACUS JAPONICUS	A,H	
1876	DIPTERYX ODORATA	A,E,H	
1877	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1878	DISODIUM COCOAMPHODIACET	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ATE		
1879	DISODIUM COCOAMPHODIPROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1880	DISODIUM DIMETICONE COPOLYOL SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 14%.
1881	DISODIUM EDETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1882	DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
1883	DISODIUM GUANYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
1884	DISODIUM INOSINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1885	DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1886	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1887	DISODIUM OLEAMIDO PEG-2 SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye. The concentration in the medicine must be no more than 1%.
1888	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in a medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1889	DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1890	DISODIUM RUTINYL DISULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
1891	DISODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1892	DISPERSIBLE CELLULOSE	E	
1893	DISTARCH PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 4%.
1894	DISTEARDIMONIUM HECTORITE	E	Only for use in topical medicines for dermal application and not to be included for medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1895	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1896	DISTEARYL PHTHALIC ACID AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1897	DISTEARYLDIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1898	DIVINYLDIMETHICONE/DIMETHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1899	DL-ALPHA-TOCOPHEROL	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
1900	DL-ALPHA-TOCOPHERYL ACETATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
1901	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
1902	DL-BORNEOL	E	
1903	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1904	DL-THREONINE	A,E	
1905	DOCOSAHEXAENOIC ACID (DHA)-RICH OIL DERIVED FROM MICROALGAE SCHIZOCHYTRIUM SP.	A	Only for use in oral medicines and must be present in combination with other ingredients.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1906	DOCUSATE SODIUM	E	
1907	DODECAHYDRO-3A,6,6,9A-TETRAMETHYLNAPHTHO(2,1-B)FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1908	DODECANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1909	DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1910	DODECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1911	DODECYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
1912	DODECYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1913	DOLICHOS LABLAB	A,H	
1914	DOLOMITE	A,E,H	The following indications are only permitted for use when the medicine is for oral and sublingual use: (SCI-BONDIOP-PR) 'Provides a minimum daily dose of 290mg of elemental calcium. A diet deficient in calcium can lead to osteoporosis in later life' (SCI-NUMCALE-AP) 'Provides a minimum daily dose of 290mg of elemental calcium which may assist in the prevention of osteoporosis when dietary intake is inadequate.'
1915	DRACAENA DRACO	A,H	
1916	DRECHSLERA SOROKINIANA	A,H	
1917	DRIED BUTTERMILK	E	
1918	DRIED CALCIUM SULFATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of dried calcium sulfate. The percentage of calcium from dried

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calcium sulfate should be calculated based on the molecular weight of dried calcium sulfate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
1919	DRIED MAGNESIUM SULFATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of dried magnesium sulfate. The percentage of magnesium from dried magnesium sulfate should be calculated based on the molecular weight of dried magnesium sulfate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
1920	DRIMIA INDICA	A,H	
1921	DRIMIA MARITIMA	A,H	
1922	DROMETRIZOLE TRISILOXANE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in a medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			exposed to the sun' (or words to this effect).
1923	DROSERA ANGLICA	A,H	
1924	DROSERA BURMANNI	A,H	
1925	DROSERA INTERMEDIA	A,H	
1926	DROSERA RAMENTACIA	A,H	
1927	DROSERA ROTUNDIFOLIA	A,E,H	
1928	DROSERA ROTUNDIFOLIA MIS	A,H	
1929	DRY WHOLE MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
1930	DRYNARIA FORTUNEI	A,H	
1931	DRYOBALANOPS AROMATICA	A,H	
1932	DRYOPTERIS FILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1933	DULACIA INOPIFLORA	A,H	
1934	DUNALIELLA SALINA	A,E,H	
1935	DUPICAL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1936	DURVILLAEA ANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1937	DWARF PINE-NEEDLE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1938	DYSPHANIA AMBROSIOIDES	A,H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1939	ECAMSULE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in a medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1940	ECHINACEA ANGUSTIFOLIA	A,E,H	
1941	ECHINACEA PALLIDA	A,E,H	
1942	ECHINACEA PURPUREA	A,E,H	
1943	ECHINOPS SPINOSUS	A,H	
1944	ECLIPTA PROSTRATA	A,H	
1945	ECTOIN	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1946	EDETATE SODIUM	E	Only for use in topical medicines for dermal application and nasal medicines. The concentration in the medicine must be no more than 0.2%.
1947	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1948	EGG LECITHIN	A,E	
1949	EICHHORNIA CRASSIPES	A,H	
1950	ELAEAGNUS ANGUSTIFOLIA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
1951	ELAEIS GUINEENSIS	A,E,H	
1952	ELASTIN	E	Only for use in topical medicines for dermal application.
1953	ELDER FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1954	ELDER FLOWER BLACK DRY	A,E,H	
1955	ELDER FLOWER BLACK POWDER	A,H	
1956	ELECAMPANE RHIZOME DRY	A,H	
1957	ELECAMPANE RHIZOME POWDER	A,H	
1958	ELEMI OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1959	ELEMI RESINOID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1960	ELEMOL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1961	ELEOCHARIS TUBEROSA	A,H	
1962	ELETTARIA CARDAMOMUM	A,E,H	
1963	ELEUTHEROCOCCUS NODIFLORUS	A,H	
1964	ELEUTHEROCOCCUS ROOT DRY	A,H	
1965	ELEUTHEROCOCCUS ROOT POWDER	A,H	
1966	ELEUTHEROCOCCUS SENTICOSUS	A,H	
1967	ELSHOLTZIA SPLENDENS	A,H	
1968	ELYMUS REPENS	A,E,H	
1969	EMU OIL	A,E	Emu oil ingredients must meet the following two requirements: 1) the manufacturing process is to include steps such as cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and 2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			extracted were healthy and fit for human consumption.
1970	EMULSIFYING WAX	E	
1971	ENOXOLONE	E	Only for use in topical medicines for dermal application.
1972	ENZYME MODIFIED CREAM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1973	EPHEDRA DISTACHYA	A,H	Ephedrine and Pseudoephedrine (of Ephedra distachya) are mandatory components of Ephedra distachya and must be declared in the application. The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1974	EPHEDRA SINICA	A,H	Ephedrine and Pseudoephedrine (of Ephedra sinica) are mandatory components of Ephedra sinica. The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1975	EPIGAEA REPENS	A,H	
1976	EPILOBIUM ANGUSTIFOLIUM	E	Only for use in topical sunscreens for dermal application and not to be included in medicines intended for use in the eye. The extract must be processed from

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the flower, leaf and stem (herb top flowering) of the plant. The extracts used must be: 1:20 in 100% water or 1:2 in 100% water. The concentrations of Epilobium angustifolium must be no more than 0.75% for a 1:2 extract in 100% water, and 5% for a 1:20 extract in 100% water.
1977	EPILOBIUM PALUSTRE	A,H	
1978	EPILOBIUM PARVIFLORUM	A,H	
1979	EPIMEDIUM BREVICORNU	A,H	
1980	EPIMEDIUM GRANDIFLORUM	A,H	
1981	EPIMEDIUM SAGITTATUM	A,H	
1982	EPOXY CEDRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1983	EQUISETUM ARVENSE	A,E,H	
1984	EQUISETUM HIEMALE	A,H	
1985	ERGOCALCIFEROL	A,E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life' is permitted only for oral use.
1986	ERGOTHIONEINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
1987	ERIGERON BREVISCAPUS	A,H	
1988	ERIOBOTRYA JAPONICA	A,H	
1989	ERIOCAULON BUERGERIANUM	A,H	
1990	ERIODICTYON CRASSIFOLIUM	A,H	
1991	ERIODICTYON GLUTINOSUM	A,H	
1992	ERODIUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CICUTARIUM		
1993	ERUCA SATIVA	A,H	
1994	ERYTHORBIC ACID	E	
1995	ERYTHRITOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
1996	ERYTHROSINE	E	Only for use as a colour for oral and topical use.
1997	ERYTHROSINE ALUMINIUM LAKE	E	Only for use as a colour for oral and topical use.
1998	ERYTHRULOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'.
1999	ESCHSCHOLZIA CALIFORNICA	A,H	
2000	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2001	ETHANOL	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'.
2002	ETHANOL ABSOLUTE	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'
2003	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2004	ETHOHEXADIOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (EHEXAD) 'Contains ethohexadiol' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2005	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2006	ETHOXYLATED NONYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2007	ETHOXYMETHOXY CYCLODODECANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2008	ETHYL-2-METHYL-1,3-DIOXOLANE-2-ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2009	ETHYL-2-METHYL-4-PENTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
2010	ETHYL-2-METHYLPENTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2011	ETHYL (2,4-DIMETHYL-[1,3] DIOXOLAN-2-YL) ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2012	ETHYL (3AR,4S,7R,7AR)-REL-OCTAHYDRO-4,7-METHANO[3AH]INDENE-3A-CARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2013	ETHYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2014	ETHYL 2-ETHYL-6,6-DIMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2015	ETHYL 2-HEXYL	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ACETOACETATE		with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2016	ETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2017	ETHYL 2-METHYLPENTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2018	ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2019	ETHYL 2,6,6,TRIMETHYL-1,3-CYCLOHEXADIENE-1-	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CARBOXYLATE		If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2020	ETHYL 3-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2021	ETHYL 3-HYDROXYBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2022	ETHYL 3-HYDROXYHEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2023	ETHYL 3-MERCAPTOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2024	ETHYL 3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
2025	ETHYL 4,7-OCTADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2026	ETHYL ACETATE	E	The residual solvent limit for ethyl acetate is 50 mg per recommended daily dose. The concentration in the medicine must be no more than 0.5%.
2027	ETHYL ACETOACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2028	ETHYL ACRYLATE	E	
2029	ETHYL AMYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2030	ETHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2031	ETHYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2032	ETHYL BENZOYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2033	ETHYL BUTYLACETYLAMINO PROPIONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes (or words to that effect)'.
2034	ETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2035	ETHYL CAPRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2036	ETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2037	ETHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2038	ETHYL CINNAMATE	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2039	ETHYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2040	ETHYL ENANTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2041	ETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2042	ETHYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
2043	ETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2044	ETHYL ISOVALERATE	E	
2045	ETHYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2046	ETHYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
2047	ETHYL LEVULATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2048	ETHYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2049	ETHYL LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2050	ETHYL LINALYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2051	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2052	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2053	ETHYL MACADAMIATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
2054	ETHYL MALTOL	E	
2055	ETHYL MENTHANE CARBOXAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2056	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2057	ETHYL METHYLPHENYLGLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2058	ETHYL METICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2059	ETHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2060	ETHYL OLEATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2061	ETHYL ORTHO-METHOXYBENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2062	ETHYL OXYHYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2063	ETHYL PALMITATE	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2064	ETHYL PARA-ANISATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2065	ETHYL PELARGONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2066	ETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2067	ETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2068	ETHYL RICINOLEATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2069	ETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2070	ETHYL SEBACATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2071	ETHYL STEARATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2072	ETHYL SUCCINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2073	ETHYL TARTRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2074	ETHYL TRANS-2, CIS-4-DECADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2075	ETHYL TRANS-3-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2076	ETHYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
2077	ETHYL VALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2078	ETHYL VANILLIN	E	
2079	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.002%.
2080	ETHYLCELLULOSE	E	
2081	ETHYLENE BRASSYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2082	ETHYLENE GLYCOL	E	The residual solvent limit for ethylene glycol is 6.2 mg per recommended daily dose. The concentration in the medicine must be no more than 0.062%.
2083	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2084	ETHYLENE/ACRYLIC ACID COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
2085	ETHYLENE/VINYL ACETATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 16%.
2086	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2087	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
2088	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 6%.
2089	ETHYLHEXYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
2090	ETHYLHEXYL METHOXYCRYLENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in the eye. The concentration in the medicine must be no more than 10%.
2091	ETHYLHEXYL TRIAZONE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2092	ETHYLHEXYLGLYCERIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2093	ETIDRONIC ACID	E	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2094	EUCALYPTUS DIVES	A,E,H	Cineole is a mandatory component of Eucalyptus dives. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2095	EUCALYPTUS FRUTICETORUM	A,E,H	Cineole is a mandatory component of Eucalyptus fruticetorum. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2096	EUCALYPTUS GLOBULUS	A,E,H	Cineole is a mandatory component of Eucalyptus globulus. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must also have a child resistant closure.
2097	EUCALYPTUS MACRORHYNCHA	A,E,H	Cineole is a mandatory component of Eucalyptus macrorhyncha. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2098	EUCALYPTUS OIL	A,E,H	Cineole is a mandatory component of Eucalyptus oil. When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25%, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			nominal capacity of the container must be no more than 25 mL. When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' When the concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2099	EUCALYPTUS RADIATA	A,E,H	Cineole is a mandatory component of Eucalyptus radiata. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2100	EUCALYPTUS ROSTRATA	A,E,H	Cineole is a mandatory component of Eucalyptus rostrata. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2101	EUCALYPTUS TERETICORTIS	A,E,H	Cineole is a mandatory component of Eucalyptus tereticortis. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2102	EUCOMMIA ULMOIDES	A,H	
2103	EUGENOL	E	Only for use in topical medicines for dermal application. When the concentration of Eugenol in the preparation is more than 25%, the nominal capacity of the container must be no more than than 25 mL. When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15mL, a restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2104	EUGENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2105	EUONYMUS ATROPURPUREUS	A,H	
2106	EUONYMUS EUROPAEUS	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2107	EUPATORIUM FORTUNEI	A,H	
2108	EUPATORIUM JAPONICUM	A,H	
2109	EUPATORIUM PERFOLIATUM	A,H	
2110	EUPATORIUM PURPUREUM	A,H	
2111	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			or - (SHELL) 'Contains crustacean shellfish'.
2112	EUPHORBIA CYPARISSIAS	A,H	
2113	EUPHORBIA DRY	A,H	
2114	EUPHORBIA HETERODOXA	A,H	
2115	EUPHORBIA HIRTA	A,H	
2116	EUPHORBIA LATHYRIS	A,H	Levodopa (of Euphorbia lathyris) is a mandatory component of Euphorbia lathyris. The concentration of Levodopa (of Euphorbia lathyris) in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%.
2117	EUPHORBIA PEKINENSIS	A,H	
2118	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2119	EUPHORBIA POWDER	A,H	
2120	EUPHORBIA RESINIFERA	A,H	
2121	EUPHORBIA SIEBOLDIANA	A,H	
2122	EUPHRASIA OFFICINALIS	A,H	
2123	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2124	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2125	EURYALE FEROX	A,H	
2126	EUTERPE OLERACEA	A	The herbal substance must be derived from the fruit only.
2127	EVENING PRIMROSE OIL	A,E,H	
2128	EVERNIA PRUNASTRA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2129	FABIANA IMBRICATA	A,H	
2130	FAGOPYRUM ESCULENTUM	A,H	
2131	FAGUS GRANDIFOLIA	A,H	
2132	FAGUS SYLVATICA	A,H	
2133	FALLOPIA JAPONICA	A,E,H	
2134	FALLOPIA MULTIFLORA	A,H	When for oral use, the medicine requires the following warning statement on the medicine label: - (FALLMUL) 'Warning: Fallopia multiflora may harm the liver in some people. Use under the supervision of a healthcare professional.'
2135	FARNESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2136	FAST GREEN FCF	E	Permitted for use as a colour for oral and topical use.
2137	FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2138	FENCHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2139	FENCHYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2140	FENNEL BITTER SEED DRY	A,E,H	
2141	FENNEL LEAF	E	
2142	FENNEL OIL	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2143	FENNEL SWEET SEED DRY	A,E,H	
2144	FENUGREEK	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2145	FENUGREEK OIL	E	Fenugreek oil is permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2146	FERRIC AMMONIUM CITRATE	A,E,H	When for internal use, iron is a mandatory component of ferric ammonium citrate. The percentage of iron from ferric ammonium citrate should be calculated based on the molecular weight of ferric ammonium citrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2147	FERRIC CHLORIDE	A,E,H	When for internal use, iron is a mandatory component of ferric chloride. The percentage of Iron from ferric

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			chloride should be calculated based on the molecular weight of ferric chloride. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2148	FERRIC CHLORIDE HEXAHYDRATE	A,E,H	When for internal use, iron is a mandatory component of ferric chloride hexahydrate. The percentage of iron from ferric chloride hexahydrate should be calculated based on the molecular weight of ferric chloride hexahydrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2149	FERRIC GLYCEROPHOSPHATE	A,E,H	When for internal use, iron is a mandatory component of ferric glycerophosphate. The percentage of iron from ferric glycerophosphate should be calculated based on the molecular

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			weight of ferric glycerophosphate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2150	FERRIC OXIDE	E	
2151	FERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2152	FERRIC PYROPHOSPHATE	A,H	When for internal use, iron is a mandatory component of ferric pyrophosphate. The percentage of Iron from ferric pyrophosphate should be calculated based on the molecular weight of ferric pyrophosphate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2153	FERROSOFERRIC OXIDE	E	When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content. When used in divided preparations

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2154	FERROSOFERRIC PHOSPHATE	H	Only for use as an active homoeopathic ingredient.
2155	FERROUS FUMARATE	A,H	When for internal use, iron is a mandatory component of ferrous fumarate. The percentage of Iron from ferrous fumarate should be calculated based on the molecular weight of ferrous fumarate. The following indications are only permitted when the medicine is for oral or sublingual use:- (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2156	FERROUS GLUCONATE	A,E,H	When for internal use, iron is a mandatory component of ferrous gluconate. The percentage of Iron from ferrous gluconate should be calculated based on the molecular weight of ferrous

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			gluconate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2157	FERROUS GLUCONATE DIHYDRATE	A,E,H	When for internal use, iron is a mandatory component of ferrous gluconate dihydrate. The percentage of Iron from ferrous gluconate dehydrate should be calculated based on the molecular weight of ferrous gluconate dihydrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2158	FERROUS IODIDE	H	Only for use as an active homoeopathic ingredient.
2159	FERROUS LACTATE TRIHYDRATE	A,E,H	When for internal use, iron is a mandatory component of ferrous lactate trihydrate. The amount of iron in the active ingredient should be calculated based on the molecular weight of ferrous

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			lactate trihydrate. When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than1%). Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2160	FERROUS PHOSPHATE OCTAHYDRATE	A,E,H	When for internal use, iron is a mandatory component of ferrous phosphate octahydrate. The amount of iron in the active ingredient should be calculated based on the molecular weight of ferrous phosphate octahydrate. When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2161	FERROUS PICRATE	H	Only for use as an active homoeopathic ingredient.
2162	FERROUS SULFATE	A,E,H	When for internal use, iron is a mandatory component of ferrous sulfate. The amount of iron in the active ingredient should be calculated based on the molecular weight of ferrous

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			sulfate. When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2163	FERROUS SULFATE HEPTAHYDRATE	A,E,H	When for internal use, iron is a mandatory component of ferrous sulfate heptahydrate. The percentage of iron from ferrous sulfate heptahydrate should be calculated based on the molecular weight of ferrous sulfate heptahydrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2164	FERULA ASSA-FOETIDA	A,E,H	
2165	FERULA FOETIDA	A,E,H	
2166	FERULA GALBANIFLUA	A,E,H	
2167	FERULA RUBRICAULIS	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2168	FERULA SUMBUL	A,H	
2169	FERULIC ACID	E	Only for use in topical medicines for dermal application.
2170	FESTUCA ELATIOR	A,H	
2171	FEVERFEW HERB DRY	A,H	
2172	FEVERFEW HERB POWDER	A,H	
2173	FICUS CARICA	A,E,H	
2174	FICUS PUMILA	A,H	
2175	FIG	E	
2176	FIG DRY	A,H	
2177	FILIPENDULA ULMARIA	A,H	
2178	FIR BALSAM ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2179	FIR NEEDLE OIL CANADIAN	A,E	
2180	FIR NEEDLE OIL SIBERIAN	A,E	
2181	FIRMIANA SIMPLEX	A,E,H	
2182	FISH OIL - RICH IN OMEGA-3 ACIDS	A	Only for use in oral medicines.
2183	FLEMINGIA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	MACROPHYLLA		
2184	FLOUVE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2185	FLUORESCEIN SODIUM	E	
2186	FOENICULUM VULGARE	A,E,H	
2187	FOLIC ACID	A	When for internal use, the maximum recommended daily dose must be no more than 500 micrograms of folic acid. When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per daily dose. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects: a) the maximum daily dose must provide 400 – 500 micrograms of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			folic acid; and b) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'; and - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet'. The following indications are permitted only when the medicine is for oral or sublingual use: - (FOLIC1) 'Source of folic acid. Can assist in maintaining normal blood.' - (VIT2) 'May assist in the management of dietary folate deficiency.' - (FOLIC2) 'Source of folic acid. Can assist in maintaining normal blood. Blood tonic.'
2188	FOOD ORANGE 6	E	Permitted for use as a colour for oral and topical use.
2189	FOOD ORANGE 7	E	Permitted for use as a colour for oral and topical use.
2190	FOOD RED 13	E	Permitted for use as a colour for topical use.
2191	FORMALDEHYDE/MEL	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	AMINE/TOSYLAMIDE COPOLYMER		dermal application. The concentration in the medicine must be no more than 10%.
2192	FORMIC ACID	H	Only for use as an active homoeopathic ingredient.
2193	FORSYTHIA SUSPENSA	A,H	
2194	FORTIFIED WINE	E	Ethanol is a mandatory component of Wine - fortified. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'
2195	FRACTIONATED COCONUT OIL	E	
2196	FRACTIONATED PALM KERNEL OIL	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2197	FRAGARIA CHILOENSIS	A,E,H	
2198	FRAGARIA VESCA	A,E,H	
2199	FRAGARIA VIRGINIANA	A,E,H	
2200	FRAGARIA X	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ANANASSA		
2201	FRANGULA BARK DRY	A,H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems'
2202	FRANGULA BARK POWDER	A,H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Frangula bark powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems'
2203	FRANGULA PURSHIANA	A,H	When for oral use, hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of Frangula purshiana. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product [or words to that effect]' - (S) 'If symptoms persist consult your healthcare practitioner [or words to that effect]'. When promoted or marketed as a laxative, the medicine requires the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			following warning statement on the medicine label: - (LAX1) 'Drink plenty of water [or words to that effect]' When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water [or words to that effect]' - (LAX2) 'Prolonged use may cause serious bowel problems'
2204	FRAXINUS AMERICANA	A,H	
2205	FRAXINUS CHINENSIS SUBSP. RHYNCHOPHYLLA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2206	FRAXINUS EXCELSIOR	A,H	The components Nuzhenide and secoiridoid glucoside GL3 are only available when the plant part is seed.
2207	FRAXINUS ORNUS	A,H	
2208	FRITILLARIA CIRRHOSA	A,H	
2209	FRITILLARIA THUNDBERGII	A,H	
2210	FRITILLARIA VERTICILLATA	A,H	
2211	FRUCTOOLIGOSACCHARIDES	A,E	
2212	FRUCTOSE	A,E,H	
2213	FUCUS VESICULOSUS	A,E,H	Iodine is a mandatory component of Fucus vesiculosus. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2214	FUMARIA OFFICINALIS	A,E,H	
2215	FUMARIC ACID	E,H	Only for use as an active homoeopathic or excipient

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			ingredient.
2216	FUMITORY HERB DRY	A,H	
2217	FUMITORY HERB POWDER	A,H	
2218	FURAMINTON	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2219	FURFURAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2220	FURFURYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2221	FURFURYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2222	FURFURYL MERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2223	FUSEL OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2224	GALBANUM OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2225	GALBANUM PHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2226	GALBANUM RESIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
2227	GALBANUM RESINOID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2228	GALEGA OFFICINALIS	A,H	
2229	GALEOPSIS SEGETUM	A,H	
2230	GALIUM APARINE	A,H	
2231	GALIUM ODORATUM	A,H	
2232	GALIUM PALUSTRE	A,H	
2233	GALIUM VERUM	A,H	
2234	GALL STONE	H	Only for use as an active homoeopathic ingredient.
2235	GALPHIMIA GLAUCA	A,H	
2236	GAMMA-4-DIMETHYL-3-CYCLOHEXENE-1-PROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2237	GAMMA-BUTYROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2238	GAMMA-CYCLODEXTRIN	E	
2239	GAMMA-DECALACTONE	E	Only for use in topical medicines for dermal application.
2240	GAMMA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2241	GAMMA-HEPTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2242	GAMMA-HEXALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2243	GAMMA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2244	GAMMA-LINOLEIC ACID	E	Only for use in topical medicines for dermal application.
2245	GAMMA-LINOLENIC ACID	E	
2246	GAMMA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2247	GAMMA-NONALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2248	GAMMA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2249	GAMMA-TERPINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2250	GAMMA-TOCOPHEROL	E	
2251	GAMMA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2252	GAMMA-VALEROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2253	GANODERMA LUCIDUM	A,E,H	
2254	GARCINIA GUMMI-GUTTA	A	Only for use in oral medicines. Must be obtained from the rind of the fruit only. Must not contain any directions for use for children or pregnant or lactating women.
2255	GARCINIA QUAESITA	A,H	
2256	GARDEN BEAN	E	
2257	GARDENIA JASMINOIDES	A,E	
2258	GARDENIA TAHITENSIS FLOWER EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%
2259	GARLIC BULB DRY	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2260	GARLIC BULB FRESH	A,H	
2261	GARLIC BULB POWDER	A,E,H	
2262	GARLIC CLOVE POWDER	A,H	
2263	GARLIC OIL	A,E,H	
2264	GASTRODIA ELATA	A,H	
2265	GAULTHERIA PROCUMBENS	A,E,H	Methyl salicylate is a mandatory component of Gaultheria procumbens and must be declared in the application. The concentration of Methyl salicylate in the medicine must be no more than 0.001%. When the concentration of Methyl salicylate in a liquid preparation is more than 5%, and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of Methyl salicylate in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging but the delivery device must be engaged into the container in such a way that prevents it from being readily removed, direct suction through the delivery device results in delivery of no more than one dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2266	GELATIN	A,E	
2267	GELIDIUM AMANSII	A,H	Iodine is a mandatory component of Gelidium amansii. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2268	GELLAN GUM	E	
2269	GELSEMIUM DRY	A,H	The concentration of Gelsemium dry in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
2270	GELSEMIUM POWDER	A,H	
2271	GELSEMIUM SEMPERVIRENS	A,H	The concentration of equivalent dry Gelsemium sempervirens in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.
2272	GENET ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
2273	GENTIAN DRY	A,H	
2274	GENTIAN POWDER	A,H	
2275	GENTIANA LUTEA	A,E,H	
2276	GENTIANA MACROPHYLLA	A,H	
2277	GENTIANA RHODANTHA	A,H	
2278	GENTIANA SCABRA	A,H	
2279	GENTIANELLA AMARELLA	A,H	
2280	GERANIAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2281	GERANIC ACID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2282	GERANIOL	E	Only for use in topical medicines for dermal application.
2283	GERANIUM	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
2284	GERANIUM MACULATUM	A,E,H	
2285	GERANIUM OIL	A,E,H	
2286	GERANIUM OIL SAPONIFIED	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2287	GERANIUM OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2288	GERANIUM ROBERTIANUM	A,E,H	
2289	GERANIUM ROSE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2290	GERANIUM SIBIRICUM	A,E,H	
2291	GERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2292	GERANYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2293	GERANYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2294	GERANYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2295	GERANYL ETHYL	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ETHER		ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2296	GERANYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2297	GERANYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2298	GERANYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
2299	GERANYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2300	GERANYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2301	GERANYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2302	GEUM RIVALE	A,H	
2303	GEUM URBANUM	A,H	
2304	GHATTI GUM	A,E,H	
2305	GIGARTINA MAMILLOSA	A,H	Iodine is a mandatory component of Gigartina mamillosa. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2306	GINGER DRY	A,E,H	
2307	GINGER OIL	A,E,H	
2308	GINGER OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
2309	GINGER POWDER	A,E,H	
2310	GINKGO BILOBA	A,E,H	The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27), as in force or existing from time to time. This condition does not apply to powdered or dried leaf.
2311	GLACIAL ACETIC ACID	E,H	The concentration in the medicine must be no more than 1.5%.
2312	GLECHOMA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HEDERACEA		
2313	GLECHOMA LONGITUBA	A,H	
2314	GLEDITSIA AUSTRALIS	A,H	
2315	GLEDITSIA SINENSIS	A,H	
2316	GLEHNIA LITTORALIS	A,H	
2317	GLORIOSA SUPERBA	A,H	Colchicine is a mandatory component of Gloriosa superba and must be declared in the application. The concentration of colchicine in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2318	GLUCOMANNAN	E	Only for use when the dosage form is other than tablet.
2319	GLUCONOLACTONE	E	
2320	GLUCOSAMINE HYDROCHLORIDE	A,E	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2321	GLUCOSAMINE SULFATE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2322	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE	A	Potassium chloride is a mandatory component of glucosamine sulfate potassium chloride. When derived from seafood, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. When for oral use, the medicine requires the following warning statement on the medicine label: - (POTAS) ‘Contains [amount of potassium in milligrams] mg of potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.’
2323	GLUCOSAMINE SULFATE SODIUM CHLORIDE	A	When derived from seafood, the medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
2324	GLUCOSE	A,E,H	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2325	GLUCOSE GLUTAMATE	E	Only for use in topical medicines for dermal application.
2326	GLUCOSE MONOHYDRATE	A,E,H	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose monohydrate, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2327	GLUCOSYLRUTIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2328	GLUTAMIC ACID	A,E	Only for use in topical medicines for dermal application.
2329	GLUTAMIC ACID HYDROCHLORIDE	A,E,H	
2330	GLUTAMINE	A,E,H	
2331	GLUTARAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2332	GLUTATHIONE	A,E	When used as an active ingredient, glutathione can only be used in medicines with an oral route of administration and must be indicated for use in adults only and not in pregnant or lactating women. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (ADULT) 'Adults only' (or words to that effect).
2333	GLUTEN-FREE WHEAT STARCH	E	
2334	GLYCERETH-26	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 7%.
2335	GLYCEROL	A,E	When used as an active ingredient, it is only for use in topical medicines for dermal application.
2336	GLYCEROL ESTER OF PARTIALLY HYDROGENATED GUM ROSIN	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Glycerol Ester of Partially Hydrogenated Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia-National Formulary, as in force or existing from time to time.
2337	GLYCERYL BEHENATE	E	Behenic acid is a mandatory component of calcium behenate. When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid. In medicines for topical use, the concentration of glyceryl behenate must be no more than 5%.
2338	GLYCERYL CAPRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 1%.
2339	GLYCERYL DIISOSTEARATE	E	For use in topical medicines for dermal application.
2340	GLYCERYL DILAURATE	E	Only for use in topical medicines for dermal application.
2341	GLYCERYL DIOLEATE	E	Only for use in topical medicines for dermal application.
2342	GLYCERYL DISTEARATE	E	Only for use in topical medicines for dermal application.
2343	GLYCERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2344	GLYCERYL ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5.5%.
2345	GLYCERYL LAURATE	E	Only for use in topical medicines for dermal application.
2346	GLYCERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2347	GLYCERYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2348	GLYCERYL MONOOLEATE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2349	GLYCERYL MONOSTEARATE	E	
2350	GLYCERYL MYRISTATE	E	Only for use in topical medicines for dermal application.
2351	GLYCERYL OLEATE CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4% of the formulation.
2352	GLYCERYL PALMITO-STEARATE	E	
2353	GLYCERYL POLYACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
2354	GLYCERYL POLYMETHACRYLATE	E	Only for use in topical medicines for dermal application.
2355	GLYCERYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2356	GLYCERYL ROSINATE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Glycerol Ester of Gum Rosin monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia-National Formulary , as in force or existing from time to time.
2357	GLYCERYL SORBITAN OLEOSTEARATE	E	Only for use in topical medicines for dermal application.
2358	GLYCERYL STARCH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 4%. The residual levels of epichlorohydrin are to be kept below the level of detection.
2359	GLYCERYL STEARATE CITRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
2360	GLYCERYL TRIACETYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 6%.
2361	GLYCERYL TRIACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
2362	GLYCERYL TRINITRATE	H	Only for use as an active homoeopathic ingredient.
2363	GLYCERYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration of glyceryl undecylenate in a medicine must be no more than 3%.
2364	GLYCINE	A,E	
2365	GLYCINE MAX	A,E,H	
2366	GLYCOGEN	E	Only for use in topical medicines for dermal application.
2367	GLYCOL DISTEARATE	E	Only for use in topical medicines for dermal application.
2368	GLYCOLIC ACID	E	Only for use in topical medicines for dermal application. Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When present as an excipient in sunscreens, the concentration in the medicine must be no more than 5%. When used as an excipient ingredient in other medicines the concentration in the medicine must be no more than 20%. If the concentration is more than 5% but no more than 20%, the pH of the medicine must be 3.5 or greater.
2369	GLYCYRRHIZA GLABRA	A,E,H	
2370	GLYCYRRHIZA SPECIES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
2371	GLYCYRRHIZA URALENSIS	A,E,H	
2372	GLYCYRRHIZINIC ACID	E	
2373	GNAPHALIUM AFFINE	A,H	
2374	GNAPHALIUM POLYCEPHALUM	A,H	
2375	GNAPHALIUM ULIGINOSUM	A,H	
2376	GOAT	H	Only for use as an active homoeopathic ingredient.
2377	GOAT MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2378	GOLD	E,H	Only for use as an active homoeopathic or excipient ingredient.
2379	GOLD CHLORIDE	H	Only for use as an active homoeopathic ingredient.
2380	GOLDEN ROD HERB DRY	A,E,H	
2381	GOLDEN SEAL ROOT DRY	A,H	
2382	GOLDEN SEAL ROOT	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	POWDER		
2383	GOLDEN SYRUP	E	Sucrose is a mandatory component of Golden syrup when the route of administration of the medicine is oral or sublingual. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2384	GOMPHRENA GLOBOSA	A,H	
2385	GOOSEBERRY	E	
2386	GOSSYPIUM HERBACEUM	A,E,H	
2387	GRAPE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2388	GRAPE SEED OIL	E	
2389	GRAPE WINE RED	E	Ethanol is a mandatory component of Grape wine red. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2390	GRAPE WINE SHERRY	E	Ethanol is a mandatory component of Grape wine sherry. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2391	GRAPE WINE WHITE	E	Ethanol is a mandatory component of Grape wine white. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
2392	GRAPEFRUIT	E	
2393	GRAPEFRUIT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2394	GRAPEFRUIT OIL COLDPRESSED	A,E,H	
2395	GRAPEFRUIT OIL CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2396	GRAPEFRUIT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2397	GRAPEFRUIT OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2398	GRAPHITE	H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			homoeopathic ingredient.
2399	GRATIOLA LINIFOLIA	A,H	
2400	GREATER NETTLE HERB DRY	A,H	
2401	GREATER NETTLE HERB POWDER	A,H	
2402	GREATER NETTLE ROOT DRY	A,H	
2403	GREATER NETTLE ROOT POWDER	A,H	
2404	GREEN LIPPED MUSSEL	A	
2405	GREEN LIPPED MUSSEL DRIED	A	
2406	GREEN LIPPED MUSSEL OIL	A	
2407	GREEN S	E	Only for use as a colour in topical and oral medicines.
2408	GRIFOLA FRONDOSA	A	When the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: -(WARF) 'Do not take while on warfarin therapy without medical advice.'
2409	GRINDELIA CAMPORUM	A,H	
2410	GRINDELIA ROBUSTA	A,H	
2411	GRISALVA	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2412	GROUND IVY HERB DRY	A,H	
2413	GROUND IVY HERB POWDER	A,H	
2414	GUAIAC WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2415	GUAIACOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
2416	GUAIACUM OFFICINALE	A,E,H	
2417	GUAIACUM RESIN	A,E,H	
2418	GUAIACUM SANCTUM	A,H	
2419	GUAIACWOOD ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2420	GUAIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2421	GUAIYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2422	GUANINE	E	Only for use as an excipient in topical medicines for dermal application.
2423	GUANOSINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.01% in the medicine.
2424	GUAR GUM	A,E,H	
2425	GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	E	Only for use as an excipient in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2426	GUAREA RUSBYI	A,H	
2427	GUAVA	E	
2428	GURJUN BALSAM	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2429	GYMNEMA SYLVESTRE	A,H	
2430	GYMNOCLADUS DIOICA	A,H	
2431	GYNOSTEMMA PENTAPHYLLUM	A	The herbal substance must be derived from the aerial parts of the vine only (stem, leaves, fruit).
2432	GYNURA JAPONICA	A,H	
2433	HAHNEMANN'S SOLUBLE MERCURY	H	Only for use as an active homoeopathic ingredient.
2434	HALIBUT-LIVER OIL	A,E	Colecalciferol and Vitamin A are mandatory components of Halibut-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			micrograms retinol equivalents for men.' When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life' is permitted only for oral use.
2435	HAMAMELIS LEAF DRY	A,H	
2436	HAMAMELIS LEAF POWDER	A,H	
2437	HAMAMELIS VIRGINIANA	A,E,H	
2438	HAMAMELIS WATER	A,E,H	
2439	HANDROANTHUS HEPTAPHYLLUS	A,H	
2440	HANDROANTHUS IMPETIGINOSUS	A,E,H	
2441	HARD FAT	E	
2442	HARD PARAFFIN	E	
2443	HARICOT BEAN	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2444	HARPAGOPHYTUM PROCUMBENS	A,E,H	
2445	HARUNGANA MADAGASCARIENSIS	A,H	
2446	HAZEL NUT	E	
2447	HAZEL NUT OIL	E	
2448	HEAVY KAOLIN	E	
2449	HEAVY MAGNESIUM OXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of heavy magnesium oxide. The percentage of magnesium from heavy magnesium oxide should be calculated based on the molecular weight of heavy magnesium oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2450	HECTORITE	E	Only for use in topical medicines for dermal application.
2451	HEDEOMA PULEGIOIDES	A	
2452	HEDERA HELIX	A,H	Emetine is a mandatory component of Hedera helix. The concentration of emetine in the medicine must be no more than 0.2%.
2453	HEDTA	E	Only for use as an excipient in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			application.
2454	HEKLA LAVA	H	Only for use as an active homoeopathic ingredient.
2455	HELESTRALIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2456	HELIANTHEMUM NUMMULARIUM	A,H	
2457	HELIANTHUS ANNUUS	A,E,H	
2458	HELIANTHUS TUBEROSUS	A,H	
2459	HELICHRYSUM ANGUSTIFOLIUM	A,E,H	
2460	HELICHRYSUM ARENARIUM	A,H	
2461	HELIOTROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2462	HELLEBORUS NIGER	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
2463	HELLEBORUS VIRIDIS	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2464	HELONIAS RHIZOME DRY	A,H	
2465	HELONIAS RHIZOME POWDER	A,H	
2466	HEMIDESMUS INDICUS	A,E,H	
2467	HEPTANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2468	HEPTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2469	HEPTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2470	HEPTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2471	HEPTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2472	HEPTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2473	HEPTYL UNDECYLENATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of the medicine must be no more than 25%.
2474	HERACLEUM HEMSLEYANUM	A,H	
2475	HERNIARIA GLABRA	A,H	
2476	HESPERIDIN	A,E	
2477	HEX-3-ENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2478	HEXAHYDRO-4,7-METHANOINDEN-6-YL PIVALATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2479	HEXAMETHYLINDANOPYRAN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2480	HEXAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2481	HEXANE	E	The concentration of the medicine must be no more than 0.029%. When used for a route of administration other than topical, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			residual solvent limit for Hexane is 2.9 mg per recommended daily dose.
2482	HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2483	HEXANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2484	HEXASODIUM FYTATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of Hexasodium fytate in the medicine must be no more than 1.0 %.
2485	HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2486	HEXYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2487	HEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2488	HEXYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2489	HEXYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
2490	HEXYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2491	HEXYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2492	HEXYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2493	HEXYL LAURATE	E	Only for use as an excipient in topical medicines for dermal application.
2494	HEXYL NICOTINATE	E	
2495	HEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2496	HEXYL TIGLATE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2497	HEXYLDECANOL	E	Only for use as an excipient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration of the medicine must be no more than 3%.
2498	HEXYLENE GLYCOL	E	Only for use as an excipient in topical medicines for dermal application.
2499	HIBISCUS ESCULENTUS	A,H	
2500	HIBISCUS MUTABILIS	A,H	
2501	HIBISCUS ROSA-SINENSIS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2502	HIBISCUS SABDARIFFA	A,E,H	
2503	HIERACIUM PILOSELLA	A,H	
2504	HIGH AMYLOSE MAIZE STARCH	A,E,H	
2505	HIGH CHROMIUM YEAST	A,E	Chromium is a mandatory component of high chromium yeast.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The maximum daily dose of chromium from high chromium yeast must be no more than 50 micrograms as high chromium yeast is considered to be an organic form of chromium. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2506	HIGH FRUCTOSE MAIZE SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2507	HIGH MOLYBDENUM YEAST	A,E	Molybdenum is a mandatory component of high molybdenum yeast. The maximum daily dose of molybdenum from high molybdenum yeast must be no more than 62.5 micrograms. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2508	HIGH SELENIUM YEAST	A	When for oral or sublingual use, selenium is a mandatory component of high selenium yeast. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2509	HIMATANTHUS LANCIFOLIUS	A,E,H	
2510	HIPPOPHAE RHAMNOIDES	A,E,H	
2511	HIRSCHFELDIA INCANA	A,H	Allyl isothiocyanate is a mandatory component of Hirschfeldia incana when the plant part is seed. When the herbal substance is derived from the seed, the maximum recommended daily dose must be no more than 20mg of allyl isothiocyanate.
2512	HISTAMINE DIHYDROCHLORIDE	H	Only for use as an active homoeopathic ingredient.
2513	HISTIDINE	A	
2514	HISTIDINE HYDROCHLORIDE	A,E,H	
2515	HO LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2516	HO WOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2517	HOLCUS LANATUS	A,H	
2518	HOLY THISTLE HERB DRY	A,H	
2519	HOLY THISTLE HERB POWDER	A,H	
2520	HOMALOMENA OCCULTA	A,H	
2521	HOMOSALATE	A,E	Only for use as an active ingredient in sunscreens. In other products, only for use as an excipient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration of homosalate in the medicine must be no more than 15%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2522	HONEY	A,E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2523	HONEY BEE	H	Only for use as an active homoeopathic ingredient.
2524	HONEY EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration of the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 1%.
2525	HONEY POWDER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2526	HOP STROBILE DRY	A,H	
2527	HOP STROBILE POWDER	A,H	
2528	HOPS OIL	A,E,H	
2529	HORDEUM DISTICHON	A,E,H	Gluten is a mandatory component when the plant part is seed, and must be declared in the application when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
2530	HORDEUM VULGARE	A,E,H	Gluten is a mandatory component when the plant part is seed, and must be declared in the application when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
2531	HOREHOUND EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2532	HORSE RADISH	E,H	Volatile oil components (of Armoracia rusticana) is a mandatory component of Horse radish. The maximum recommended daily dose must be no more than 20 mg of volatile oil components (of Armoracia rusticana).
2533	HOTTONIA PALUSTRIS	A,H	
2534	HOUTTUYNIA CORDATA	A,H	
2535	HOVENIA DULCIS	A,H	
2536	HUMULUS LUPULUS	A,E,H	
2537	HYALURONIC ACID	E	Only for use as an excipient in topical medicines for dermal application.
2538	HYDNOCARPUS ANTHELMINTICA	A,H	When the medicine is for other than topical use and the plant part is seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry seed.
2539	HYDRANGEA ARBORESCENS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2540	HYDRANGEA PANICULATA	A,H	
2541	HYDRASTIS CANADENSIS	A,E,H	
2542	HYDRATED SILICA	E	Only for use when the route of administration is other than inhalation.
2543	HYDROCHLORIC ACID	E,H	Only for use as an active homoeopathic ingredient. The concentration of the medicine must be no more than 0.5%.
2544	HYDROCOTYLE UMBELLATA	A,H	
2545	HYDROFLUORIC ACID	H	Only for use as an active homoeopathic ingredient.
2546	HYDROGEN CYANIDE	H	Only for use as an active homoeopathic ingredient.
2547	HYDROGEN PEROXIDE	A,E	When used as the active ingredient, it is only for use in topical medicines for dermal application. The concentration of hydrogen peroxide in the medicine must be no more than 3%. When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2548	HYDROGENATED BUTYLENE/ETHYLENE /STYRENE COPOLYMER	E	Only for use in topical medicines for dermal application. The combined concentration of hydrogenated butylene/ethylene/stryene copolymer and hydrogenated ethylene/propylene/styrene copolymer in the medicine must be no more than 9%.
2549	HYDROGENATED C6-14 OLEFIN POLYMERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
2550	HYDROGENATED CASTOR OIL	E	
2551	HYDROGENATED COCO-GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2552	HYDROGENATED COCONUT OIL	E	
2553	HYDROGENATED COTTONSEED OIL	E	
2554	HYDROGENATED DIMER DILINOLEYL/DIMETH YLCARBONATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 4% in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			product.
2555	HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	E	The combined concentration of ethylene/propylene/styrene copolymer - hydrogenated must be no more than 9%.
2556	HYDROGENATED LANOLIN	E	
2557	HYDROGENATED LECITHIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2558	HYDROGENATED PALM GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.6%.
2559	HYDROGENATED PALM KERNEL OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.
2560	HYDROGENATED PALM OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. Polycyclic aromatic hydrocarbons

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be kept below the level of detection.
2561	HYDROGENATED POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
2562	HYDROGENATED POLYISOBUTENE	E	Only for use in topical medicines for dermal application.
2563	HYDROGENATED SOYA OIL	E	
2564	HYDROGENATED TALLOW GLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2565	HYDROGENATED VEGETABLE OIL	E	
2566	HYDROLIAC	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2567	HYDROLYSED ADANSONIA DIGITATA LEAF POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%
2568	HYDROLYSED ALGIN	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%
2569	HYDROLYSED CEREAL SOLIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2570	HYDROLYSED COLLAGEN	E	
2571	HYDROLYSED ELASTIN	E	Only for use in topical medicines for dermal application.
2572	HYDROLYSED GELATIN	A,E	
2573	HYDROLYSED GLYCOSAMINOGLYCANS	E	Only for use in topical medicines for dermal application.
2574	HYDROLYSED JOJOBA ESTERS	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2575	HYDROLYSED KERATIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2576	HYDROLYSED MAIZE STARCH	E	
2577	HYDROLYSED MILK PROTEIN	E	
2578	HYDROLYSED RICE	A,E,H	
2579	HYDROLYSED RICE PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%.
2580	HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
2581	HYDROLYSED VEGETABLE PROTEIN	E	
2582	HYDROLYSED WHEAT PROTEIN	E	When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
2583	HYDROLYSED WHEAT PROTEIN/PVP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2584	HYDROLYSED YEAST PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
2585	HYDROQUINONE DIMETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2586	HYDROUS WOOL FAT	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2587	HYDROXOCOBALAMIN	A	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2588	HYDROXYACETOPHENONE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
2589	HYDROXYAPATITE	A,E	The following indications are only permitted when the medicine is for oral and sublingual use: - (SCI-BONDIOP-PR) 'A diet deficient in calcium can lead to osteoporosis in later life' - (SCI-NUMCALE-AP) 'Calcium may help prevent osteoporosis when dietary intake is inadequate' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2590	HYDROXYCITRATE COMPLEX	A	Hydroxycitrate complex must contain one or more of the three salts (calcium, sodium or potassium hydroxycitrate) of hydroxycitric acid.
2591	HYDROXYCITRIC ACID	A	
2592	HYDROXYCITRONELLAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2593	HYDROXYCITRONELLAL-METHYLANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2594	HYDROXYCITRONELLAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2595	HYDROXYCITRONELLOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2596	HYDROXYETHYL CETEARAMIDOPROPYLDIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2597	HYDROXYETHYL UREA	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 1%.
2598	HYDROXYLATED LANOLIN	E	
2599	HYDROXYLATED MILK GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.1%.
2600	HYDROXYLYSINE	A,E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2601	HYDROXYMETHYLCELLULOSE	E	
2602	HYDROXYOCTACOSANYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
2603	HYDROXYPALMITOYL SPHINGANINE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 0.1%.
2604	HYDROXYPROLINE	A,E	
2605	HYDROXYPROPYL DISTARCH PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 4%.
2606	HYDROXYPROPYL STARCH	E	
2607	HYDROXYPROPYLBETADEX	E	Only for use in topical medicines for dermal application.
2608	HYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 9%.
2609	HYETELLOSE	E	
2610	HYLOCEREUS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	UNDATUS		
2611	HYMETELLOSE	E	
2612	HYOSCAMUS LEAF DRY	A,H	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscyamus leaf dry. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscine in the medicine must be no more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2613	HYOSCAMUS LEAF POWDER	A,H	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscamus leaf powder. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of hyoscine in the medicine must be no more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2614	HYOSCYAMUS NIGER	A,H	Alkaloids calculated as hyoscyamine and hyoscine are mandatory components of Hyoscyamus niger. The concentration of hyoscyamine in the medicine must be no more than 3 micrograms/kg or 3 micrograms/L or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			0.3%. The concentration of hyoscine in the medicine must be no more than than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
2615	HYPERICUM ASCYRON	A,H	
2616	HYPERICUM JAPONICUM	A,H	
2617	HYPERICUM PERFORATUM	A,E,H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
2618	HYPROLOSE	E	
2619	HYPROMELLOSE	E	
2620	HYPROMELLOSE PHTHALATE	E	
2621	HYPTIS SUAVEOLENS	A,H	
2622	HYSSOPUS OFFICINALIS	A,E,H	
2623	IBERIS AMARA	A,H	
2624	ICHTHAMMOL	H	Only for use as an active homoeopathic ingredient.
2625	ILEX AQUIFOLIUM	A,H	
2626	ILEX CHINENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2627	ILEX PARAGUARIENSIS	A,E,H	Caffeine is a mandatory component of Ilex paraguariensis. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
2628	ILEX ROTUNDA	A,H	
2629	ILEX VERTICILLATA	A,H	
2630	ILLICIUM VERUM	A,H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 50 millilitres. When the concentration of Illicium verum oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
2631	IMIDUREA	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (IMIDUR) 'Contains imidurea [or words to that effect]'.
2632	IMMORTELLE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2633	IMMORTELLE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2634	IMPATIENS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2635	IMPATIENS BALSAMINA	A,H	
2636	IMPATIENS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	GLANDULIFERA		
2637	IMPERATA CYLINDRICA	A,E,H	
2638	INDIGO CARMINE	E	Permitted for use as a colour for oral and topical use.
2639	INDIGO CARMINE ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
2640	INDIGOFERA TINCTORIA	A,H	
2641	INDISAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2642	INDOLE	E,H	Only for use as an active homoeopathic or excipient ingredient. The maximum recommended daily dose must contain no more than 75 mg indole.
2643	INDOLENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2644	INDUSTRIAL METHYLATED SPIRIT	E	
2645	INOSITOL	A,E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2646	INULA BRITANNICA	A,H	
2647	INULA HELENIUM	A,E,H	
2648	INULA RACEMOSA	A,H	
2649	INULIN	A,E	
2650	INVERT SUGAR	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
2651	INVERT SYRUP	E	Glucose is a mandatory component of Invert syrup when the route of administration is oral or sublingual.
2652	IODINE	H	Only for use as an active homoeopathic ingredient. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2653	IODOPROPYNYL BUTYLCARBAMATE	E	For use as an excipient ingredient in topical medicines only. The concentration in aqueous medicines must be no more than 10%.
2654	IONONE	E	Only for use in topical medicines for dermal application.
2655	IOPAMIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2656	IPECACUANHA DRY	A,H	Emetine is a mandatory component of Ipecacuanha Dry. The concentration of emetine in the medicine must be no more than 0.2%.
2657	IPECACUANHA POWDER	A,H	Emetine is a mandatory component of Ipecacuanha Powder. The concentration of emetine in the medicine must be no more than 0.2%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2658	IPECACUANHA PREPARED	A,H	Emetine is a mandatory component of Ipecacuanha Prepared. The concentration of emetine in the medicine must be no more than 0.2%.
2659	IPECACUANHA ROOT LIQUID EXTRACT	A,H	Emetine is a mandatory component of Ipecacuanha root liquid extract. The concentration of emetine in the medicine must be no more than 0.2%.
2660	IPOMOEA BATATAS	A,H	
2661	IPOMOEA JALAPA	A,H	
2662	IRIDOPHYCUS FLACCIDUM	A,H	Iodine is a mandatory component of Iridophycus flaccidum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is more than 2.5%. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2663	IRIS DOMESTICA	A,H	
2664	IRIS FLORENTINA	A,H	
2665	IRIS GERMANICA	A,H	
2666	IRIS PALLIDA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2667	IRIS TENAX	H	
2668	IRIS VERSICOLOR	A,H	
2669	IRON	A,H	Only for use in oral medicines. When used as an active ingredient, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than1%). Divided preparations with a dose of more than 5mg of elemental iron per dosage unit and more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2670	IRON (II) BISGLYCINE SULFATE TRIHYDRATE	A	Only for use in oral medicines. Iron is a mandatory component of iron (II) bisglycine sulfate trihydrate and availability is restricted to use as a source of the relevant mineral only. The percentage of iron from iron (II) bisglycine sulfate trihydrate should be calculated based on the molecular weight of iron (II) bisglycine sulfate trihydrate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2671	IRON (II) GLYCINATE	A	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Iron is a mandatory component of iron (II) glycinate and availability is restricted to use as a source of the relevant mineral only. The percentage of iron from iron (II) glycinate should be calculated based on the molecular weight of iron (II) glycinate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2672	IRON (III) GLYCINATE	A	Only for use in oral medicines. Iron is a mandatory component of iron (III) glycinate and availability is restricted to use as a source of the relevant mineral only. The percentage of Iron from iron (III) glycinate should be calculated based on the molecular weight of iron (III) glycinate. When for internal use, the medicine must contain a daily dose of no more than 24 mg of iron. If the divided dosage form contains more than 5 mg of iron per dosage unit (excluding up to 10 mg of iron oxide when used as an excipient), the primary pack must contain no more

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			than 750 mg of iron. In undivided preparations, the primary pack must contain no more than 750 mg of iron (excluding iron oxides when present as an excipient at a quantity of no more than 1%). Divided preparations with a dose of more than 5 mg of elemental iron per dosage unit and more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. Undivided preparations containing more than 250 mg of elemental iron in the total contents of the container are required to have a child resistant closure. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			deficiency.'
2673	IRON AMINO ACID CHELATE	A,H	Only for use in oral medicines. When used internally, iron is a mandatory component of iron amino acid chelate. The concentration of iron in iron amino acid chelate must be no more than 25%. The following indications are only permitted when the medicine is for oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic.' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2674	IRON OXIDE BLACK	E	Permitted for use as a colour for oral and topical use. When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2675	IRON OXIDE RED	E	Permitted for use as a colour for oral and topical use. When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content. When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2676	IRON OXIDE YELLOW	E	Permitted for use as a colour for oral and topical use. When used in undivided preparations for internal use and the concentration of iron oxide in the medicine is more than 1%, it is considered part of the total iron content. When used in divided preparations for internal use, the concentration in the medicine must be no more than 10 mg per dosage unit.
2677	IRON PHOSPHATE	A,E,H	When used internally, iron is a mandatory component of iron phosphate and must be declared. The concentration of iron in iron phosphate must be no less than 16%. The following indications are only permitted when the medicine is for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			oral or sublingual use: - (SUPMIN) 'For mineral (may state the mineral) supplementation.' - (IRON1) 'Source of iron. Can assist in maintaining normal blood.' - (IRON2) 'Source of iron. Can assist in maintaining normal blood. Blood tonic.' - (IRON5) 'Source of iron. Iron is necessary for the formation of haemoglobin which transports oxygen to the tissues.' - (IRON6) 'May assist in the management of dietary iron deficiency.'
2678	IRONE	E	
2679	IRVINGIA GABONENSIS SEED TRIGLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 0.375%.
2680	ISATIS TINCTORIA	A,H	
2681	ISOAMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
2682	ISOAMYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2683	ISOAMYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2684	ISOAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2685	ISOAMYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2686	ISOAMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2687	ISOAMYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2688	ISOAMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
2689	ISOAMYL CITRONELLYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2690	ISOAMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2691	ISOAMYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2692	ISOAMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2693	ISOAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2694	ISOAMYL LAURATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 12%.
2695	ISOAMYL METHOXYCINNAMATE	A	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 10%.
2696	ISOAMYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2697	ISOAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2698	ISOAMYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2699	ISOBERGAMIATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2700	ISOBORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2701	ISOBORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2702	ISOBORNYL CYCLOHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2703	ISOBUTANE	E	Only for use in topical medicines for dermal application.
2704	ISOBUTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2705	ISOBUTYL ALCOHOL	E	The residual solvent limit for Isobutyl alcohol is 50mg per recommended daily dose. The concentration of isobutyl alcohol must be no more than 0.5% of the formulation.
2706	ISOBUTYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2707	ISOBUTYL BENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2708	ISOBUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2709	ISOBUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
2710	ISOBUTYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2711	ISOBUTYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2712	ISOBUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
2713	ISOBUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2714	ISOBUTYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2715	ISOBUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2716	ISOBUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2717	ISOBUTYL QUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2718	ISOBUTYL SALICYLATE	E	Only for use in topical medicines for dermal application.
2719	ISOBUTYLENE/ISOPRENE COPOLYMER	E	Only for oral use when the dosage form is chewing gum. The concentration must be consistent with best practice for the production of gum delivery systems.
2720	ISOBUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2721	ISOBUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2722	ISOCETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2723	ISOCETYL LINOLEOYL STEARATE	E	Only for use in topical medicines for dermal application.
2724	ISOCETYL STEARATE	E	Only for use in topical medicines for dermal application.
2725	ISOCETYL STEAROYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			intended for use in the eye. The concentration must be no more than 10%.
2726	ISOCYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2727	ISODECYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
2728	ISODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2729	ISODECYL OLEATE	E	Only for use in topical medicines for dermal application.
2730	ISODECYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 2%.
2731	ISODODECANE	E	Only for use in topical medicines for dermal application.
2732	ISOEICOSANE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 2%.
2733	ISOEUGENOL	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2734	ISOEUGENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2735	ISOEUGENYL BENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2736	ISOHEXADECANE	E	Only for use in topical medicines for dermal application.
2737	ISOJASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2738	ISOLEUCINE	A,E	
2739	ISOMALT	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.
2740	ISOMENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2741	ISOMETHYLIONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2742	ISONONYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
2743	ISONONYL ISONONANOATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration must be no more than 15%.
2744	ISOPENTANE	E	For dental use only. The concentration must be no more than 2%.
2745	ISOPENTANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2746	ISOPHORONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2747	ISOPHYTOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2748	ISOPROPYL-3-METHYL-BUTANE THIOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2749	ISOPROPYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2750	ISOPROPYL 4-HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			contains one hydroxybenzoate source.
2751	ISOPROPYL ACETATE	E	Only for use in topical medicines for dermal application.
2752	ISOPROPYL ALCOHOL	E	
2753	ISOPROPYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2754	ISOPROPYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2755	ISOPROPYL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
2756	ISOPROPYL LANOLATE	E	Only for use in topical medicines for dermal application.
2757	ISOPROPYL LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 5.6%.
2758	ISOPROPYL MYRISTATE	E	
2759	ISOPROPYL PALMITATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2760	ISOPROPYL PPG-2 ISODECETH-7 CARBOXYLATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration must be no more than 10%.
2761	ISOPROPYL STEARATE	E	Only for use in topical medicines for dermal application.
2762	ISOPROPYL TITANIUM TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.2%.
2763	ISOPULEGOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2764	ISORALDEINE 70	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2765	ISOSTEARIC ACID	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2766	ISOSTEAROYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 0.3%.
2767	ISOSTEARYL ALCOHOL	E	Only for use in topical medicines for dermal application.
2768	ISOSTEARYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
2769	ISOSTEARYL PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 2%.
2770	ISOTRIDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2771	ISOVALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2772	ISOVALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2773	ISPAGHULA HUSK DRY	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
2774	ISPAGHULA HUSK POWDER	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
2775	IVA AXILLARIS	A,H	
2776	JAMAICA DOGWOOD BARK DRY	A,H	
2777	JAMAICA DOGWOOD BARK POWDER	A,H	
2778	JASMINE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2779	JASMINE LACTONE	E	Only for use in topical medicines for dermal application.
2780	JASMINE OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2781	JASMINUM GRANDIFLORUM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2782	JASMINUM OFFICINALE	A,E,H	
2783	JASSOLIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2784	JATEORHIZA PALMATA	A,H	
2785	JATROPHA CURCAS	H	Only for use as an active homoeopathic ingredient

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2786	JERUSALEM ARTICHOKE	E	
2787	JOJOBA ESTERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 25%.
2788	JUGLANS CINEREA	A,E,H	
2789	JUGLANS NIGRA	A,E,H	
2790	JUGLANS REGIA	A,H	
2791	JUNCUS EFFUSUS	A,H	
2792	JUNIPER BERRY OIL	A,E,H	
2793	JUNIPER BERRY OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2794	JUNIPERUS CALIFORNICA	A,H	
2795	JUNIPERUS COMMUNIS	A,E,H	
2796	JUNIPERUS MEXICANA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2797	JUNIPERUS OXYCEDRUS	A,H	
2798	JUNIPERUS VIRGINIANA	A,E,H	
2799	JUSTICIA ADHATODA	A,H	

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2800	KADSURA COCCINEA	A,H	
2801	KAEMPFERIA GALANGA	A,H	
2802	KALMIA LATIFOLIA	A,H	
2803	KAOLIN	E	
2804	KELP DRY	A,H	Iodine is a mandatory component of Kelp dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2805	KELP POWDER	A,E,H	Iodine is a mandatory component of Kelp powder. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2806	KERATIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2807	KEROSENE	E,H	Only for use as a homoeopathic ingredient. When used in liquid preparations, the concentration in the medicine must be no more than 25%.
2808	KIDNEY BEAN	E	
2809	KIRSCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2810	KIWI FRUIT	E	
2811	KNAUTIA ARVENSIS	A,H	
2812	KOREAN GINSENG ROOT DRY	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2813	KOREAN GINSENG ROOT POWDER	A,H	
2814	KRAMERIA IXIENA	A,H	
2815	KRAMERIA LAPPACEA	A,H	
2816	KUNZEA AMBIGUA	A	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only' - (UNDILU) 'Not to be applied undiluted to the skin except on the advice of a health care practitioner'. When the dosage form is other than essential oil, the maximum concentration in topical medicines must be no more than 25% w/w and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2817	L-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2818	L-BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2819	L-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2820	L-LIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
2821	L-LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2822	L-MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2823	L-MENTHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2824	L-ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
2825	LABDANUM ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2826	LABDANUM GUM EXTRACT ETHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance and the total fragrance concentration in a medicine is no more than 1%.
2827	LABDANUM OIL	A,E,H	
2828	LABURNUM ANAGYROIDES	A,H	Sparteine is a mandatory component of Laburnum anagyroides. The concentration of sparteine in the medicine must be no more than 0.001%.
2829	LACTALBUMIN	E	
2830	LACTIC ACID	A,E,H	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the finished medicine is safe for its intended purpose.
2831	LACTITOL MONOHYDRATE	E	The medicine requires the following warning statements on the medicine label: - (SUGOLS) 'Medicines containing lactitol monohydrate may have a laxative effect or cause diarrhoea' (or words to that effect) - (LACT) 'Contains lactose' (or words to that effect) - (COWMK) 'Derived from cows milk'.
2832	LACTOBACILLUS ACIDOPHILUS	A	
2833	LACTOBACILLUS AMYLOVORUS	A	
2834	LACTOBACILLUS BREVIS	A	
2835	LACTOBACILLUS CASEI	A	
2836	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2837	LACTOBACILLUS CRISPATUS	A	
2838	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2839	LACTOBACILLUS DELBRUECKII SSP	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	LACTIS		
2840	LACTOBACILLUS FERMENTUM	A	
2841	LACTOBACILLUS GALLINARUM	A	
2842	LACTOBACILLUS GASSERI	A	
2843	LACTOBACILLUS HELVETICUS	A	
2844	LACTOBACILLUS JOHNSONII	A	
2845	LACTOBACILLUS KEFIRANOFACIENS	A	
2846	LACTOBACILLUS KEFIRGRANUM	A	
2847	LACTOBACILLUS KEFIRI	A	
2848	LACTOBACILLUS PARACASEI	A	
2849	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2850	LACTOBACILLUS PLANTARUM	A	
2851	LACTOBACILLUS REUTERI	A	
2852	LACTOBACILLUS RHAMNOSUS	A	
2853	LACTOBACILLUS SALIVARIUS SSP	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	SALICINIUS		
2854	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2855	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2856	LACTOSCATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2857	LACTOSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars [or words to that effect]' if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose [or words to that effect]'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2858	LACTOSE MONOHYDRATE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose monohydrate, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars [or words to that effect]' if medicine contains two or more sugars. If one of the sugars is lactose monohydrate then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose monohydrate [or words to that effect]'.
2859	LACTUCA SATIVA	A,H	
2860	LACTUCA VIROSA	A,H	
2861	LACTULOSE	E	
2862	LACTULOSE SOLUTION	A	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
2863	LAGENARIA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	VULGARIS		
2864	LAMINARIA CLOUSTONI	A,E,H	Iodine is a mandatory component of Laminaria cloustoni. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2865	LAMINARIA DIGITATA	A,E,H	Iodine is a mandatory component of Laminaria digitata and must be declared in the application. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2866	LAMINARIA JAPONICA	A,E,H	Iodine is a mandatory component of Laminaria japonica. Only for external use when the concentration of iodine in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2867	LAMIUM ALBUM	A,H	
2868	LANETH-5	E	Only for use in topical medicines for dermal application.
2869	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2870	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2871	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2872	LANTANA CAMARA	A,H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2873	LARIX ARABINOGALACTAN	A,E	Only for use in oral medicines. The ingredient must be derived from Larix occidentalis or Larix larcinia. The maximum recommended daily dose must be no more than 15 grams. The concentration of polysaccharides in the medicine must be equal to or more than 85%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2874	LARIX DECIDUA	A,H	
2875	LARIX KAEMPFERI	A,H	The maximum recommended daily dose must be no more than 1 mg of the equivalent dry herbal material of Larix kaempferi.
2876	LARREA TRIDENTATA	A,H	The medicine requires the following warning statement on the medicine label: - (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.
2877	LATHYRUS SATIVUS	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lathyrus sativus. The medicine must not contain lathyrogenic amino acids.
2878	LAURAMINE OXIDE	E	
2879	LAUREL LEAF OIL	A,H	
2880	LAURETH-10	E	Only for use in topical medicines for dermal application.
2881	LAURETH-12	E	Only for use in topical medicines for dermal application.
2882	LAURETH-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.4%. Residual levels of ethylene oxide

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(and related substances) must be kept below the level of detection.
2883	LAURETH-23	E	Only for use in topical medicines for dermal application.
2884	LAURETH-3	E	Only for use in topical medicines for dermal application.
2885	LAURETH-4	E	Only for use in topical medicines for dermal application.
2886	LAURETH-7	E	Only for use in topical medicines for dermal application.
2887	LAURETH-8	E	
2888	LAURIC ACID	A,E	When for use as an active ingredient is for use in oral medicines only and the maximum recommended daily dose must not exceed 1500 mg.
2889	LAURIL MACROGOL 400 DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
2890	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2891	LAUROYL LYSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.75%.
2892	LAURUS NOBILIS	A,E,H	When the plant preparation is oil or distillate, the nominal capacity of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			container must be no more than 25 millilitres. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is less than or equal to 15 millilitres, a restricted flow insert must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is greater than 15 millilitres, a child resistant closure must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25%, the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
2893	LAURYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
2894	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2895	LAURYL GLUCOSIDE	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 12%.
2896	LAURYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
2897	LAURYL PCA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
2898	LAURYL PEG-10 TRIS(TRIMETHYLSILOXY)SILYLETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 2%.
2899	LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
2900	LAURYL PEG/PPG-18/18 METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 9%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2901	LAURYL POLYGLUCOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must not exceed 1% in leave-on medicines and 3% in wash-on/wash-off medicines.
2902	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2903	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2904	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED SOY	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	PROTEIN		use in the eye. The concentration in the medicine must be no more than 0.007%.
2905	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2906	LAVANDIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2907	LAVANDIN OIL ABRIAL	A,E,H	
2908	LAVANDIN OIL GROSSO	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2909	LAVANDULA ANGUSTIFOLIA	A,E,H	Camphor is a mandatory component of Lavandula angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container.
2910	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A,E,H	Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container.
2911	LAVANDULA X INTERMEDIA	A,E,H	Camphor is a mandatory component of Lavandula x intermedia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oil or distillates, the concentration of camphor must be no more than 2.5%. .
2912	LAVENDER OIL	A,E,H	Camphor is a mandatory component of lavender oil. In solid and semi solid preparations,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
2913	LAWSONIA INERMIS	A,H	
2914	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2915	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2916	LEAF ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2917	LECITHIN	A,E	
2918	LEDEBOURIELLA SESELOIDES	A,H	
2919	LEDUM GROENLANDICUM	A,H	
2920	LEDUM PALUSTRE	A,H	When the route of administration is other than topical, the maximum recommended daily dose must be no more than 0.001mg of the equivalent dry herbal material of Ledum

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			palustre.
2921	LEMNA MINOR	A,H	
2922	LEMON	E	When used internally, oxedrine is a mandatory component of lemon. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2923	LEMON BALM LEAF DRY	A,H	
2924	LEMON BALM LEAF POWDER	A,E,H	
2925	LEMON OIL	A,E,H	When used internally, oxedrine is a mandatory component of lemon oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) steam distilled or rectified; or b) for internal use; or c) contains 0.05% or less of lemon oil; or d) for use in soaps or bath or shower gels that are washed off the skin.
2926	LEMON OIL DISTILLED	A,E,H	When used internally, oxedrine is a mandatory component of lemon oil distilled.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2927	LEMON OIL TERPENELESS	A,E,H	When used internally, oxedrine is a mandatory component of lemon oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2928	LEMON OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2929	LEMON PEEL DRIED	A,E,H	When used internally, oxedrine is a mandatory component of lemon peel dried. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2930	LEMONGRASS OIL	A,E,H	
2931	LENS CULINARIS	A,H	
2932	LENTIL	E	
2933	LENTINULA EDODES	A,E,H	
2934	LEONTOPODIUM ALPINUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 1%.
2935	LEONURUS CARDIACA	A,E,H	
2936	LEONURUS SIBIRICUS	A,E,H	
2937	LEPIDIUM APETALUM	A,H	
2938	LEPIDIUM MEYENII	A	Only for use in oral medicines when the plant part is tuber and the plant preparation is dry. The maximum recommended daily dose must be no more than 3.5g of Lepidium meyenii dried tuber (or its extract equivalent).
2939	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2940	LEPTOSPERMUM SCOPARIUM OIL	A	Only for use as an active ingredient when the route of administration is topical or oral application in a mouthwash preparation. If the concentration is more than 25%, the nominal capacity of the container must be no more than 25mL. When the concentration is more than 25%, and the nominal capacity of the container less than 15mL, a restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken' When the concentration is more than 25%, the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
2941	LESPEDEZA CAPITATA	A,H	
2942	LETTUCE	E	
2943	LEUCINE	A,E	
2944	LEUZEA UNIFLORUM	A,H	
2945	LEVISTICUM OFFICINALE	A,H	
2946	LEVOCARNITINE	A	
2947	LEVOCARNITINE FUMARATE	A	
2948	LEVOCARNITINE HYDROCHLORIDE	A	
2949	LEVOCARNITINE MAGNESIUM CITRATE	A	
2950	LEVOCARNITINE TARTRATE	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2951	LEVOMEFOLATE CALCIUM	A,	Only for use in oral medicines. Levomefolic acid is a mandatory component of Levomefolate calcium. The maximum recommended daily dose must provide no more than 500 micrograms of Levomefolic acid from Levomefolate calcium. When folic acid, folinic acid, levomefolate salts and/or their derivatives are used in combination, the medicine must provide no more than a total of 500 micrograms of folic acid, folinic acid, levomefolate salts and/or their derivatives in total per maximum recommended daily dose. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects: a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; and b) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'; and - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			balanced diet'.
2952	LEVOMEFOLATE GLUCOSAMINE	A	Only for use in oral medicines. Levomefolic acid is a mandatory component of Levomefolate glucosamine. The maximum recommended daily dose must provide no more than 500mcg of Levomefolic acid from Levomefolate glucosamine. When used in combination with folic acid, folinic acid and/or their derivatives, the medicine must not provide more than a total of 500 mcg of folic acid, folinic acid and/or their derivatives in total per maximum recommended daily dose. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects: a) the maximum daily dose must provide 400 – 500 micrograms of folic acid; and b) the following statements must be included on the label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect)'; and - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			balanced diet'.
2953	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
2954	LEVULINIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2955	LIGHT KAOLIN	E	
2956	LIGHT LIQUID PARAFFIN	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2957	LIGHT MAGNESIUM OXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of light magnesium oxide. The percentage of magnesium from light magnesium oxide should be calculated based on the molecular weight of light magnesium oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
2958	LIGUSTICUM SINENSE	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2959	LIGUSTICUM WALLICHII	A,E,H	
2960	LIGUSTRUM LUCIDUM	A,H	
2961	LILIUM BROWNII	A,H	
2962	LILIUM CANDIDUM	A,E,H	
2963	LILIUM LANCIFOLIUM	A,H	
2964	LILIUM LONGIFLORUM	A,H	
2965	LIME FRUIT	E	
2966	LIME OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2967	LIME OIL COLDPRESSED	A,E,H	The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) contains 0.5% or less of lime oil coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
2968	LIME OIL DISTILLED	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2969	LIME OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2970	LIME OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2971	LIME TREE FLOWER DRY	A,H	
2972	LIME TREE FLOWER POWDER	A,H	
2973	LIME, ESSENCE	E	
2974	LIMES TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2975	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
2976	LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2977	LINALOOL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2978	LINALYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2979	LINALYL ACETATE	E	Only for use in topical medicines for dermal application.
2980	LINALYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2981	LINALYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2982	LINALYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2983	LINALYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2984	LINALYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2985	LINALYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2986	LINDERA STRYCHNIFOLIA	A,H	
2987	LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
2988	LINOLEIC ACID	E	
2989	LINOLENIC ACID	E	
2990	LINSEED DRY	A,E,H	
2991	LINSEED OIL	A,E,H	
2992	LINSEED POWDER	A,E,H	
2993	LINUM USITATISSIMUM	A,E,H	
2994	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline When used in an undvided preparation, the unit 'Thousand lipase units per gram' is permitted. When used in a divuded preparation,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the unit 'Thousand lipase unit' is permitted.
2995	LIQUID GLUCOSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100 mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
2996	LIQUID PARAFFIN	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2997	LIQUIDAMBAR FORMOSANA	A,H	
2998	LIQUIDAMBAR ORIENTALIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
2999	LIQUIDAMBAR STYRACIFLUA	A,E,H	
3000	LIQUIDAMBAR TAIWANIANA	A,H	
3001	LIQUIDAMBER STYRACIFLUA RESIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3002	LIQUORICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3003	LIQUORICE DRY	A,E,H	
3004	LIQUORICE LIQUID EXTRACT	A,E,H	
3005	LIQUORICE POWDER	A,E,H	
3006	LITCHI CHINENSIS	A,H	
3007	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3008	LITHOSPERMUM OFFICINALE	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3009	LITSEA CUBEBA	A,E,H	
3010	LITSEA CUBEBA OIL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3011	LOBARIA PULMONARIA	A,H	
3012	LOBELIA DRY	A,H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3013	LOBELIA INFLATA	A,H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3014	LOBELIA POWDER	A,H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3015	LOLIUM PERENNE	A,H	
3016	LOLIUM TEMULENTUM	A,H	
3017	LONGIFOLENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total longifolene concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
3018	LONICERA CAPRIFOLIUM	A,E,H	
3019	LONICERA JAPONICA	A,E,H	
3020	LONICERA PERICLYMENUM	A,H	
3021	LOPHATHERUM GRACILE	A,H	
3022	LOQUAT	E	
3023	LORANTHUS PARASITICUS	A,H	
3024	LOROPETALUM CHINENSIS	A,H	
3025	LOTUS CORNICULATUS	A,H	
3026	LOVAGE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3027	LOVAGE OIL	A,E,H	
3028	LOVAGE ROOT DRY	A,H	
3029	LOVAGE ROOT POWDER	A,H	
3030	LUDWIGIA PROSTRATA	A,H	
3031	LUFFA CYLINDRICA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3032	LUFFA PURGANS	A,H	
3033	LUTEIN	A,E,H	Permitted for use as a colour for oral and topical use.
3034	LYCHEE	E	
3035	LYCIUM BARBARUM	A,H	
3036	LYCIUM CHINENSE	A,E,H	
3037	LYCOPENE	A,E	
3038	LYCOPERSICON ESCULENTUM	A,E,H	Steroidal alkaloids calculated as solanine is a mandatory component of Lycopersicon esculentum. The maximum daily dose must not provide more than 10 mg of steroidal alkaloids calculated as solanine.
3039	LYCOPODIUM ANNOTINUM	A,H	
3040	LYCOPODIUM CLAVATUM	A,H	
3041	LYCOPODIUM COMPLANATUM	A,H	
3042	LYCOPUS EUROPAEUS	A,H	
3043	LYCOPUS LUCIDUS	A,H	
3044	LYCOPUS VIRGINICUS	A,H	Pulegone is a mandatory component of Lycopus virginicus. The concentration of pulegone in the medicine must be no more than 4%.
3045	LYGODIUM JAPONICUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3046	LYSIMACHIA CHRISTINAE	A,H	
3047	LYSIMACHIA VULGARIS	A,H	
3048	LYSINE	A,E	
3049	LYSINE HYDROCHLORIDE	A,E	
3050	LYTHRUM HYSSOPIFOLIA	A,H	
3051	LYTHRUM SALICARIA	A,H	
3052	LYTHRUM VERTICILLATUM	A,H	
3053	MACADAMIA INTEGRIFOLIA	A,E	
3054	MACADAMIA NUT	E	
3055	MACADAMIA NUT OIL	E	
3056	MACADAMIA TERNIFOLIA	A,E,H	
3057	MACE	E,H	Only for use as an active homoeopathic ingredient. Safrole is a mandatory component of Mace. When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3058	MACE OIL	A,H	Safrole is a mandatory component of Mace oil. When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%. When the concentration of mace oil in the preparation is more than 50% and the nominal capacity of the container is 25 mL or less, a restricted flow insert must be fitted on the container.
3059	MACROCYSTIS PYRIFERA	A,E,H	Iodine is a mandatory component of Macrocystis pyrifera. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3060	MACROGOL 1000	E	
3061	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3062	MACROGOL 1500	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3063	MACROGOL 1500 CASTOR OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3064	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3065	MACROGOL 20000	E	
3066	MACROGOL 300	E	
3067	MACROGOL 3000	E	
3068	MACROGOL 3350	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
3069	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3070	MACROGOL 400	E	
3071	MACROGOL 4000	E	
3072	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3073	MACROGOL 600	E	
3074	MACROGOL 6000	E	
3075	MACROGOL 600000	E	
3076	MACROGOL 800	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3077	MACROGOL 8000	E	
3078	MACROGOL 900	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.95%.
3079	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3080	MAGNESIUM AMINO ACID CHELATE	A,E,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. If used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium amino acid chelate. The quantity of magnesium in the medicine must be no more than 25%. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3081	MAGNESIUM ASCORBATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3082	MAGNESIUM ASCORBATE MONOHYDRATE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3083	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3084	MAGNESIUM ASPARTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium aspartate tetrahydrate. The percentage of Magnesium from magnesium aspartate tetrahydrate should be calculated based on the molecular weight of magnesium aspartate tetrahydrate. The indication 'For mineral (may

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.-
3085	MAGNESIUM ASPARTATE DIHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium aspartate dihydrate. The percentage of magnesium from magnesium aspartate dihydrate should be calculated based on the molecular weight of magnesium aspartate dihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3086	MAGNESIUM ASPARTATE TETRAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium aspartate tetrahydrate. The percentage of Magnesium from magnesium aspartate tetrahydrate should be calculated based on the molecular weight of magnesium aspartate tetrahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3087	MAGNESIUM CARBONATE HYDRATE	A,E,H	If used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium carbonate hydrate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The amount of magnesium in the active ingredient should be calculated based on the molecular weight of magnesium carbonate hydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3088	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	If used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium chloride 4.5-hydrate. The percentage of magnesium from magnesium chloride 4.5-hydrate should be calculated based on the molecular weight of magnesium chloride 4.5-hydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3089	MAGNESIUM CHLORIDE HEXAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium chloride hexahydrate. The percentage of magnesium from magnesium chloride hexahydrate should be calculated based on the molecular weight of magnesium chloride hexahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
3090	MAGNESIUM CITRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium citrate. The percentage of magnesium from magnesium citrate should be calculated based on the molecular weight of magnesium citrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3091	MAGNESIUM CITRATE NONAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium citrate nonahydrate. The percentage of magnesium from magnesium citrate nonahydrate should be calculated based on the molecular weight of magnesium citrate nonahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3092	MAGNESIUM CITRATE TETRADECAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium citrate tetradecahydrate. The percentage of magnesium from magnesium citrate tetradecahydrate

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			should be calculated based on the molecular weight of magnesium citrate tetradecahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3093	MAGNESIUM DIGLUTAMATE	A,E,H	The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3094	MAGNESIUM GLUCONATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium gluconate. The percentage of magnesium from magnesium gluconate should be calculated based on the molecular weight of magnesium gluconate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3095	MAGNESIUM GLYCEROPHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium glycerophosphate. The percentage of magnesium from magnesium glycerophosphate should be calculated based on the molecular weight of magnesium glycerophosphate. The indication 'For mineral (may

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3096	MAGNESIUM GLYCINATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of Magnesium glycinate. The percentage of Magnesium from Magnesium glycinate should be calculated based on the molecular weight of Magnesium glycinate The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3097	MAGNESIUM GLYCINATE DIHYDRATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of Magnesium glycinate dihydrate. Based on molecular weights the declared quantity of Magnesium from Magnesium glycinate dihydrate must be no less than 11.1% and must be no more than 12.2% of th eMagnesium glycinate dihydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3098	MAGNESIUM HYDROGEN PHOSPHATE	H	
3099	MAGNESIUM HYDROXIDE	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
3100	MAGNESIUM LYSINATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of Magnesium lysinate. The percentage of Magnesium from Magnesium lysinate should be calculated based on the molecular weight of Magnesium lysinate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3101	MAGNESIUM METHIONINATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of magnesium methioninate. The percentage of magnesium from magnesium methioninate should be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calculated based on the molecular weight of magnesium methioninate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3102	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3103	MAGNESIUM OROTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium orotate . The percentage of magnesium from Magnesium orotate should be calculated based on the molecular weight of Magnesium orotate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3104	MAGNESIUM OROTATE DIHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium orotate dihydrate. The percentage of magnesium from magnesium orotate dihydrate should be calculated based on the molecular weight of magnesium orotate dihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
3105	MAGNESIUM OXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium oxide. The percentage of Magnesium from Magnesium oxide should be calculated based on the molecular weight of Magnesium oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3106	MAGNESIUM PHOSPHATE PENTAHYDRATE	A,E,H	If used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium phosphate pentahydrate. The amount of magnesium in the active ingredient should be calculated based on the molecular weight of magnesium phosphate pentahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3107	MAGNESIUM PHOSPHATE TRIBASIC	A,E,H	Magnesium is a mandatory component of Magnesium phosphate tribasic. The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			tribasic.
3108	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of magnesium pyruvate. The percentage of magnesium from magnesium pyruvate should be calculated based on the molecular weight of pyruvate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3109	MAGNESIUM STEARATE	E	
3110	MAGNESIUM SULFATE DIHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate dihydrate. The percentage of Magnesium from Magnesium sulfate dihydrate should be calculated based on the molecular weight of Magnesium sulfate dihydrate. The indication 'For mineral (may

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3111	MAGNESIUM SULFATE HEPTAHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the preparation is intended as a mineral supplementation, magnesium is a mandatory component of magnesium sulfate heptahydrate. The percentage of Magnesium from magnesium sulfate heptahydrate should be calculated based on the molecular weight of magnesium sulfate heptahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3112	MAGNESIUM SULFATE MONOHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate monohydrate. The percentage of Magnesium from Magnesium sulfate monohydrate should be calculated based on the molecular weight of Magnesium sulfate monohydrate. The indication 'For mineral (may state the mineral) supplementation' is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			only permitted when the medicine is for oral or sublingual use.
3113	MAGNESIUM SULFATE TRIHYDRATE	A,E,H	When used internally, the maximum recommended daily dose must be no more than 1.5g. When used as an active ingredient and the medicine is intended as a mineral supplementation, magnesium is a mandatory component of Magnesium sulfate trihydrate. The percentage of Magnesium from Magnesium sulfate trihydrate should be calculated based on the molecular weight of Magnesium sulfate trihydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3114	MAGNESIUM TRISILICATE	E	
3115	MAGNOLIA GLAUCA	A,H	
3116	MAGNOLIA LILIFLORA	A,H	
3117	MAGNOLIA OBOVATA	A,H	
3118	MAGNOLIA OFFICINALIS	A,E,H	
3119	MAGNOLIA SALICIFOLIA	A,H	
3120	MAIZE	E	
3121	MAIZE BRAN	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3122	MAIZE OIL	A,E,H	
3123	MAIZE STARCH	A,E,H	
3124	MALACHITE GREEN	E	Permitted for use as a colour for topical use.
3125	MALIC ACID	E	Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
3126	MALPIGHIA GLABRA	A,E,H	
3127	MALT EXTRACT	E	
3128	MALTITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) ‘Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]’.
3129	MALTITOL SOLUTION	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) ‘Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3130	MALTODEXTRIN	E	Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3131	MALTOL	E	
3132	MALTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3133	MALTOSE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
3134	MALUS DOMESTICA	A,E,H	The concentration of amygdalin in the medicine must be no more than 0%.
3135	MALUS PUMILA	A,E,H	
3136	MALUS SYLVESTRIS	A,H	
3137	MALVA MOSCHATA	A,H	
3138	MALVA SYLVESTRIS	A,E,H	
3139	MALVA VERTICILLATA	A,H	
3140	MANDARIN	E	
3141	MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3142	MANDARIN OIL COLDPRESSED	A,E,H	When used internally, oxedrine is a mandatory component of mandarin oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3143	MANDARIN OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3144	MANDARIN RESIDUE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3145	MANDARINAL 32048	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3146	MANDRAGORA OFFICINARUM	A,H	Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum. The concentration in the medicine must be no more than 10 mg/kg or 10 mL/L or 0.001%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%. The concentration of hyoscine in the medicine must be no more than 300

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			micrograms/kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
3147	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3148	MANGANESE (II) DIASPARTATE	A,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Manganese is a mandatory component of Manganese (II) diaspartate. The percentage of Manganese from Manganese (II) diaspartate should be calculated based on the molecular weight of Manganese (II) diaspartate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3149	MANGANESE (II) GLYCINATE	A,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Manganese is a mandatory component of Manganese (II) glycinate. The percentage of Manganese from Manganese (II) glycinate should be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calculated based on the molecular weight of Manganese (II) glycinate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3150	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3151	MANGANESE AMINO ACID CHELATE	A,E,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. If used as an active ingredient and the medicine is intended as a mineral supplementation, the equivalent quantity of Manganese. The declared quantity of Manganese must be no more than 25% of the Manganese amino acid chelate in the formulation. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3152	MANGANESE CHLORIDE TETRAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, manganese is a mandatory component of manganese chloride tetrahydrate. The percentage of manganese from manganese chloride tetrahydrate should be calculated based on the molecular weight of manganese

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			chloride tetrahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3153	MANGANESE DIASPARTATE	A,E,H	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. If used as an active ingredient and the medicine is intended as a mineral supplementation, the equivalent quantity of Manganese is required. The declared quantity of Manganese must be no more than 25% of the manganese diaspartate in the formulation. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3154	MANGANESE GLUCONATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, Manganese is a mandatory component of Manganese gluconate. The percentage of Manganese from Manganese gluconate should be calculated based on the molecular weight of Manganese gluconate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
3155	MANGANESE GLYCEROPHOSPHATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, Manganese is a mandatory component of Manganese glycerophosphate. The percentage of Manganese from Manganese glycerophosphate should be calculated based on the molecular weight of Manganese glycerophosphate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3156	MANGANESE OXIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, Manganese is a mandatory component of Manganese oxide. The percentage of Manganese from Manganese oxide should be calculated based on the molecular weight of Manganese oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3157	MANGANESE SULFATE MONOHYDRATE	A,E,H	If used as an active ingredient and the medicine is intended as a mineral supplementation, manganese is a mandatory component of Manganese sulfate monohydrate. The percentage of manganese from Manganese sulfate monohydrate

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			should be calculated based on the molecular weight of Manganese sulfate monohydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3158	MANGANESE SULFATE TETRAHYDRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, manganese is a mandatory component of manganese sulfate tetrahydrate. The percentage of manganese from manganese sulfate tetrahydrate should be calculated based on the molecular weight of manganese sulfate tetrahydrate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3159	MANGIFERA INDICA	A,E,H	
3160	MANGO	E,H	
3161	MANIHOT UTILISSIMA	A,H	
3162	MANNITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			diarrhoea' (or words to that effect).
3163	MARANTA ARUNDINACEA	A,H	
3164	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3165	MARJORAM OIL SPANISH	A,E,H	When the concentration in the preparation is more than 50%, the nominal capacity of the container must be no more than 50 mL, the medicine must have a restricted flow insert fitted to the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3166	MARJORAM OIL SWEET	A,E,H	When the concentration in the preparation is more than 50%, the nominal capacity of the container must be no more than 50 mL, the medicine must have a restricted flow insert fitted to the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3167	MARRUBIUM VULGARE	A,E,H	
3168	MARSDENIA CUNDURANGO	A,H	
3169	MARSHMALLOW ROOT DRY	A,H	
3170	MARSHMALLOW	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ROOT POWDER		
3171	MARTYNIA PARVIFLORA	A,H	
3172	MASSOIA LACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3173	MASTIC	A,H	
3174	MATE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3175	MATRICARIA CHAMOMILLA	A,E,H	
3176	MATRICARIA FLOWER DRY	A,E,H	
3177	MATRICARIA RECUTITA	A,E,H	
3178	MEADOWSWEET HERB DRY	A,H	
3179	MEADOWSWEET HERB POWDER	A,H	
3180	MECOBALAMIN (CO-	A	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	METHYLCOBALAMIN)		
3181	MEDICAGO SATIVA	A,E,H	The level of l-canavanine must be no more than that of the dried leaf. When fresh leaf extract is used and the extraction ratio is between 34:1 and 46:1, the quantity of l-canavanine in the extract must not be more than that in the fresh leaf.
3182	MEDIUM CHAIN TRIGLYCERIDES	E	
3183	MELALEUCA ALTERNIFOLIA	A,E,H	Cineole is a mandatory component of Melaleuca alternifolia. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3184	MELALEUCA CAJUPUTI	A,E,H	Cineole is a mandatory component of Melaleuca cajuputi. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3185	MELALEUCA DISSITIFLORA	A,H	Cineole is a mandatory component of Melaleuca dissitiflora. In liquid preparations, when the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3186	MELALEUCA ERICIFOLIA	A,E,H	Cineole is a mandatory component of Melaleuca ericifolia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3187	MELALEUCA LINARIIFOLIA	A,H	Cineole is a mandatory component of Melaleuca linariifolia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3188	MELALEUCA OIL	A,E,H	Cineole and cajuput oil are a mandatory components of Melaleuca Oil. When the plant preparation is oil and the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3189	MELALEUCA QUINQUENERVIA	A,E,H	Cineole is a mandatory component of Melaleuca quinquenervia.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3190	MELICOPE PTELEIFOLIA	A,H	
3191	MELILOTUS OFFICINALIS	A,E,H	Coumarin is a mandatory component of Melilotus officinalis. The concentration of coumarin in the medicine must be no more than 0.001%.
3192	MELISSA OFFICINALIS	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3193	MELON	E	
3194	MENADIONE SODIUM BISULFITE	E	
3195	MENAQUINONE 7	A	For oral use only. The medicine must not provide more than 180 micrograms per maximum daily dose in adults, 90 micrograms per maximum daily dose in children between 10-18 years, and 45 micrograms per maximum daily dose in children less than 10 years of age.
3196	MENISPERMUM CANADENSE	A,H	
3197	MENTHA AQUATICA	A,H	
3198	MENTHA ARVENSIS	A,E,H	
3199	MENTHA ARVENSIS LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3200	MENTHA ARVENSIS OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3201	MENTHA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HAPLOCALYX		
3202	MENTHA PULEGIUM	A,H	D-Pulegone and volatile oil components (of Mentha pulegium) are mandatory components of Mentha pulegium. When the nominal capacity of the container is more than 15 millilitres, the concentration of D-pulegone in the medicine must be no more than 4%. When the concentration of D-Pulegone in the preparation is more than 4% and the nominal capacity of the container is 15 millilitres or less, the medicine must have a child resistant closure and restricted flow insert fitted on the container. The medicine requires the following warning statements on the medicine label: - (NTAKEN) 'Not to be taken' - (CHILD) 'Keep out of reach of children' (or words to that effect). When the medicine is for topical use, the maximum recommended daily dose must be no more than 150 mg of Mentha pulegium oil or distillate. When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Mentha pulegium oil or distillate.
3203	MENTHA SPICATA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3204	MENTHA X CARDIACA	A,E,H	
3205	MENTHA X PIPERITA	A,E,H	
3206	MENTHA X PIPERITA NOTHOSUBSP. CITRATA	A,H	
3207	MENTHADIENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3208	MENTHANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3209	MENTHOFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3210	MENTHOL	A,E	When used as an active ingredient, permitted only in medicated space sprays and medicated lozenges.
3211	MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3212	MENTHONE GLYCERINE ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3213	MENTHONE THIOL FRACTION	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3214	MENTHOXYPROPANE DIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3215	MENTHYL 2-HYDROXYETHYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3216	MENTHYL 2-HYDROXYPROPYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3217	MENTHYL ANTHRANILATE	A	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3218	MENTHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3219	MENTHYL LACTATE	E	
3220	MENYANTHES TRIFOLIATA	A,H	
3221	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3222	MERCURY	H	Only for use as an active homoeopathic ingredient.
3223	MESPILUS GERMANICA	A,H	
3224	METACRESOL	E	Only for use in topical medicines for dermal application.
3225	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3226	METHANOL	E	The residual solvent limit is 30 mg per recommended daily dose. The concentration in the medicine must be no more than 0.3%.
3227	METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 1%.
3228	METHIONINE	A,E	
3229	METHYL-3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3230	METHYL-BETA-METHYL THIOLPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3231	METHYL-PARA-TERT-BUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3232	METHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3233	METHYL 2-OCTYNOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3234	METHYL 3,6-DIMETHYLRESORCYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3235	METHYL ACETATE	E	The residual solvent limit is 50 mg per recommended daily dose. The concentration in the medicine must be no more than 0.5%.
3236	METHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3237	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3238	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3239	METHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3240	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3241	METHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3242	METHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3243	METHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3244	METHYL CARBITOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3245	METHYL CEDRYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3246	METHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3247	METHYL CIS-5-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3248	METHYL	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CYCLOPENTENOLONE		with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3249	METHYL CYCLOPENTYLIDENEACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3250	METHYL DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3251	METHYL DIHYDROABIETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3252	METHYL DIISOPROPYL PROPIONAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3253	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3254	METHYL ETHYL KETONE	E	The residual solvent limit is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
3255	METHYL EUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3256	METHYL FUROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3257	METHYL GLUCETH-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Residue levels of ethylene oxide are to be kept below the level of detection.
3258	METHYL GLUCETH-20	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
3259	METHYL GLUCETH-20 BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3260	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3261	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3262	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3263	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3264	METHYL HEPTENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3265	METHYL HEPTYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more 1%.
3266	METHYL HEXYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3267	METHYL HEXYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3268	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3269	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3270	METHYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3271	METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3272	METHYL ISOBUTYL KETONE	E	The residual solvent limit is 50 mg per maximum daily dose. The concentration in the medicine must be no more than 0.5%.
3273	METHYL ISOEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3274	METHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3275	METHYL JASMONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
3276	METHYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
3277	METHYL LINOLEATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3278	METHYL LINOLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3279	METHYL MAGNESIUM CHLORIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3280	METHYL METHACRYLATE	E	
3281	METHYL METHACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 1%.
3282	METHYL METHOXY PYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3283	METHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3284	METHYL NAPHTHYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3285	METHYL NONYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3286	METHYL NONYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3287	METHYL OCTIN CARBONATE	E	
3288	METHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3289	METHYL PHENYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3290	METHYL PHENYL CARBINYL-ISO-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3291	METHYL PHENYL GLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3292	METHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3293	METHYL PHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3294	METHYL ROSINATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3295	METHYL SALICYLATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.001%. For topical use, when the concentration in a liquid preparation is more than 5%, and the dosage form is other than spray, the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			requires child resistant packaging. For topical use, when the concentration in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging but the delivery device must be engaged into the container in such a way that prevents it from being readily removed, direct suction through the delivery device results in delivery of no more than one dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish.
3296	METHYL STEARATE	E	
3297	METHYL THIOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3298	METHYL TRIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3299	METHYLBENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3300	METHYLCELLULOSE	A,E	
3301	METHYLCHLOROISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application. The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3302	METHYLCYCLOHEXADIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3303	METHYLDIBROMO GLUTARONITRILE	E	Only for use in topical medicines for dermal application.
3304	METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYL PHENOL	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
3305	METHYLISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application. The concentration of methylisothiazolinone in the medicine must be no more than 0.01%. The total concentration of methylchloroisothiazolinone and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			methylisothiazolinone in the medicine must be no more than 0.0015%.
3306	METHYLMERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3307	METHYLPROPANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
3308	METHYLSILANOL/SILICATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3309	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3310	MICA	E	Only for use when the route of administration is oral, dental or topical. The concentration in oral medicines must be no more than 2.5%. The concentration in dental toothpastes must be no more than 0.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3311	MICROCALICIUM ARENARIUM	A,H	
3312	MICROCOCCUS LUTEUS LYSATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
3313	MICROCOS PANICULATA	A,H	
3314	MICROCRYSTALLINE CELLULOSE	E	
3315	MICROCRYSTALLINE WAX	E	Only for use as an excipient in medicines for topical, oral or oral application routes of administration. When microcrystalline wax is used as an excipient ingredient, the route of administration 'oral' is only permitted when the dosage form is 'chewing gum'.
3316	MICROSPORUM GYPSEUM	A,H	
3317	MILK FAT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3318	MILK THISTLE FRUIT DRY	A,H	
3319	MILK THISTLE FRUIT	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	POWDER		
3320	MILLET	E	
3321	MILLETTIA DIELSIANA	A,H	
3322	MIMOSA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3323	MIMULUS GUTTATUS	A,H	
3324	MINT OIL DEMENTHOLISED	A,E,H	
3325	MINTLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3326	MITCHELLA REPENS	A,H	
3327	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3328	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS	A,E	When used as an active ingredient and the route of administration is oral

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	CONCENTRATE		or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3329	MIXED TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3330	MODIFIED FOOD STARCH	E	
3331	MOLASSES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3332	MOLYBDENUM	H	Only for use as an active homoeopathic ingredient. When Molybdenum is sourced from Molybdenum trioxide then the maximum daily dose must be no more than 125 micrograms. When Molybdenum is sourced from yeast - high molybdenum then the maximum recommended daily dose must be no more than 62.5 micrograms.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3333	MOLYBDENUM TRIOXIDE	A	Molybdenum is a mandatory component of Molybdenum trioxide. The maximum daily dose of molybdenum from Molybdenum trioxide must be no more than 125 micrograms. The percentage of molybdenum from molybdenum trioxide should be calculated based on the molecular weight of molybdenum trioxide.
3334	MOMORDICA BALSAMINA	A,H	
3335	MOMORDICA CHARANTIA	A,H	
3336	MOMORDICA COCHINCHINENSIS	A,H	When Lycopene, Lutein or Betocarotene are declared as components, the plant part is restricted to fruit flesh, fruit peel or seed aril.
3337	MONARDA DIDYMA	A,H	
3338	MONO- AND DI-GLYCERIDES	E	
3339	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3340	MONOBASIC CALCIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, calcium is a mandatory component of monobasic calcium phosphate. The percentage of calcium from monobasic calcium phosphate should be calculated based on the molecular

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			weight of monobasic calcium phosphate. The following indications are only permitted when the medicine is for oral and sublingual use: - (OSPOR1) 'Source of calcium. May assist in the prevention and/or treatment of osteoporosis' - (OSPOR2) 'Source of calcium. Women's calcium requirements are increased after menopause. Calcium supplementation may be of assistance in the prevention and/or treatment of osteoporosis' - (CALC1) 'Source of calcium. Women's calcium requirements are increased after menopause' - (CALC2) 'Source of calcium. A calcium supplement formulated to strengthen bone and tissue in growing and mature users. (or) Source of calcium. A calcium supplement formulated to strengthen bone and tissue for children and older adults' - (CALC3) 'Source of calcium. Adequate dietary calcium in our youth and throughout life is required to maximise bone' - (CALC4) 'Source of calcium. A diet deficient in calcium can lead to osteoporosis in later life.' The indication 'For mineral (may state the mineral) supplementation' is only permitted for use when the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine is for oral or sublingual use.
3341	MONOBASIC DIHYDRATE SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
3342	MONOBASIC POTASSIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of monobasic potassium phosphate. The percentage of potassium from monobasic potassium phosphate should be calculated based on the molecular weight of monobasic potassium phosphate. When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 11.5. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
3343	MONOBASIC SODIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, sodium is a mandatory component of monobasic sodium phosphate. The percentage of sodium from monobasic sodium phosphate should be calculated based on the molecular weight of monobasic sodium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
3344	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3345	MONOPHOSPHOTHIAMINE	A	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3346	MONOPHOSPHOTHIAMINE DIHYDRATE	A	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3347	MONOPOTASSIUM GLUTAMATE	A,E	
3348	MONOSODIUM DIHYDROGEN CITRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
3349	MONOSODIUM GLUTAMATE MONOHYDRATE	A,E	
3350	MONSTERA DELICIOSA	A,H	
3351	MONTAN WAX	E	
3352	MORDANT RED 11	E	Permitted for use as a colour for topical use. The concentration in the medicine must be no more than 0.05%.
3353	MORINDA CITRIFOLIA	A,H	Only for use when the plant part is fruit and the plant preparation is fruit juice or fruit powder. Fruit powder must be produced by freeze drying the whole fruit (excluding the seeds).
3354	MORINDA OFFICINALIS	A,H	
3355	MORINGA OLEIFERA	A,H	
3356	MORUS ALBA	A,H	
3357	MORUS BOMBYCIS	A,H	
3358	MORUS NIGRA	A,E,H	
3359	MOSKENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
3360	MOTHERWORT HERB DRY	A,H	
3361	MOTHERWORT HERB POWDER	A,H	
3362	MUCUNA PRURIENS	A,H	Levodopa (of Mucuna pruriens) is a mandatory component of Mucuna pruriens. The concentration of Levodopa (of Mucuna pruriens) in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.
3363	MULBERRY	E	
3364	MUNG BEAN	E	
3365	MURRAYA KOENIGII	A,H	
3366	MURRAYA PANICULATA	A,H	
3367	MUSA X PARADISIACA	A,H	
3368	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3369	MUSK TIBETENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3370	MUSK XYLOL	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3371	MUSKS	H	Only for use as an active homoeopathic ingredient.
3372	MUSTARD	E	Allyl isothiocyanate is a mandatory component of Mustard. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
3373	MUSTARD OIL	E	Allyl isothiocyanate is a mandatory component of Mustard oil. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
3374	MUSTARD SEED OIL	E	Allyl isothiocyanate is a mandatory component of Mustard seed oil. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
3375	MYOSOTIS ARVENSIS	A,H	
3376	MYRCENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3377	MYRCENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 1%.
3378	MYRICA CERIFERA	A,E,H	
3379	MYRISTIC ACID	E	
3380	MYRISTIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3381	MYRISTICA FRAGRANS	A,E,H	Safrole is a mandatory component of Myristica fragrans. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%. When the plant preparation is oil or distillate and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect).
3382	MYRISTYL ALCOHOL	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
3383	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3384	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3385	MYROXYLON BALSAMUM	A,E,H	
3386	MYROXYLON BALSAMUM VAR. PEREIRAE	A,H	
3387	MYRRH	A,H	
3388	MYRRH OIL	A,E,H	
3389	MYRRH RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3390	MYRRHIS ODORATA	A,H	
3391	MYRSINE AFRICANA	A,H	
3392	MYRTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3393	MYRTENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3394	MYRTLE ESSENCE MAX	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3395	MYRTLE OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3396	MYRTUS COMMUNIS	A,E,H	
3397	N-BUTYL SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3398	N-HEXYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
3399	N-NONYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3400	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3401	NARDOSTACHYS CHINENSIS	A,H	
3402	NARINGIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3403	NASTURTIUM OFFICINALE	A,E,H	
3404	NATURAL CHERRY FLAVOUR	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3405	NATURAL FISH OIL	A,E	When therapeutic indications for this product are made against Vitamin A or colecalciferol (Vitamin D), they

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			are mandatory components of fish oil - natural. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’ The indication 'Vitamin D helps calcium absorption (or words of like intent)' and 'A diet deficient in calcium can lead to osteoporosis in later life' are permitted only for oral use.
3406	NAUCLEA OFFICINALIS	A,H	
3407	NELUMBO NUCIFERA	A,H	
3408	NELUMBO NUCIFERA FLOWER WAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3409	NEOHESPERIDIN-DIHYDROCHALCONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%
3410	NEOMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3411	NEOPENTYL GLYCOL DIHEPTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 25%.
3412	NEOPENTYL GLYCOL DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3413	NEOPENTYL GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 5%.
3414	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3415	NEOPICRORHIZA SCROPHULARIIFLORA	A,H	
3416	NEPETA CATARIA	A,H	Pulegone is a mandatory component of Nepeta cataria and must be declared in the application. The concentration of pulegone in the medicine must be no more than 4%.
3417	NERAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3418	NERIUM OLEANDER	A,H	The concentration of equivalent dry Nerium oleander in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3419	NEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3420	NEROLIDOL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3421	NERYL-ISO-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3422	NERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3423	N-GLUCONYL ETHANOLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3424	NICKEL	H	Only for use as an active homoeopathic ingredient.
3425	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3426	NICOTINAMIDE	A,E,H	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3427	NICOTINAMIDE ASCORBATE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3428	NICOTINIC ACID	A,E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3429	NIGELLA DAMASCENA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3430	NIGELLA SATIVA	A,E,H	
3431	NIGRITELLA ANGUSTIFOLIA	A,H	
3432	NITRIC ACID	E,H	Only for use as an active homoeopathic ingredient. The concentration of nitric acid in the medicine must be no more than 0.5%.
3433	NONADIENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3434	NONANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3435	NONANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
3436	NONFAT DRY MILK	E,H	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
3437	NONIVAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3438	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3439	NONOXINOL 12	E	For use in hand scrub formulations for healthcare professionals only. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3440	NONOXINOL 5	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3441	NONOXINOL 9	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 25%.
3442	NONYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3443	NOOTKATONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3444	NOPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3445	NORDIHYDROGUAIARETIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3446	NOTOPTERYGIUM FORBESII	A,H	
3447	NOTOPTERYGIUM INCISIUM	A,H	
3448	NUPHAR JAPONICA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3449	NUPHAR LUTEA	A,H	
3450	NUTMEG DRY	A,E,H	Safrole is a mandatory component of Nutmeg Dry. When for internal use then the concentration of safrole from all ingredients in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole from all ingredients in the medicine must be no more than 1%.
3451	NUTMEG OIL	A,E,H	Safrole is a mandatory component of Nutmeg oil. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%. When the concentration of Nutmeg oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3452	NUTMEG POWDER	A,E,H	Safrole is a mandatory component of Nutmeg powder. When for internal use then the concentration of safrole in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3453	NUX VOMICA DRY	A,H	Strychnine (of Strychnos spp.) is a mandatory component of Nux Vomica Dry. The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3454	NUX VOMICA POWDER	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Nux Vomica Powder. The concentration in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3455	NYCTANTHES ARBOR-TRISTIS	A,H	
3456	NYLON	E	Only for use in topical medicines for dermal application.
3457	NYLON-12	E	Only for use in topical medicines for dermal application.
3458	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3459	NYMPHAEA ALBA	A,E,H	
3460	NYMPHAEA CAERULEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine to be no more than 0.3%. Only for use in liquid extracts where the plant part is the flower and the solvent in 100% water.
3461	NYMPHAEA ODORATA	A,H	
3462	OAK CHIPS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3463	OAKMOSS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3464	OAKMOSS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3465	OAT	E,H	Only for use as a homoeopathic ingredient. Gluten is a mandatory component of Oat when the route of administration is other than topical and mucosal.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When the route of administration is other than topical or muscosal, the medicine requires the warning statement: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3466	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3467	OATMEAL COLLOIDAL	A,E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3468	OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3469	OCIMENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3470	OCIMUM BASILICUM	A,E,H	When the plant preparation is oil or distillate, Methyl chavicol, eugenol, methyleugenol and cineole are mandatory components of Ocimum basilicum. The concentration of methyleugenol in the medicine must not exceed 1%. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25 millilitres or less, a restricted flow insert must be fitted on the container, and requires the following warning statement on the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). When the concentration of cineole OR eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of eugenol and the concentration of eugenol in the product must not be greater than 25%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3471	OCIMUM KILIMANDSCHARICUM	A,H	Camphor is a mandatory component of Ocimum kilimandscharicum. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container.
3472	OCIMUM MINIMUM	A,H	
3473	OCIMUM	A,H	When the plant part is oil or distillate, eugenol is a mandatory component of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TENUIFLORUM		Ocimum tenuiflorum. When the concentration of eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When the preparation is for topical use in the mouth, the preparation may not contain more than 5 mL of eugenol and the concentration of eugenol in the product must not be greater than 25%.
3474	OCOTEA ODORIFERA	A,H	Safrole is a mandatory component of Ocotea odorifera. When for internal use then the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3475	OCTACOSANOL	E	
3476	OCTADECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3477	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3478	OCTAHYDRO-4,7-METHANO-3AH-INDENE-3A-CARBOXYLIC ACID, ETHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3479	OCTAHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3480	OCTAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3481	OCTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3482	OCTANOHYDROXAMIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3483	OCTANOIC ACID	A	Only for use in oral and topical medicines. When for topical use, the concentration in the medicine must be no more than 2% (w/w).
3484	OCTHILINONE	E	Only for use in topical medicines for dermal application.
3485	OCTOCRYLENE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
3486	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3487	OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3488	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3489	OCTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3490	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3491	OCTYL METHOXYCINNAMATE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 10%.
3492	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3493	OCTYL SALICYLATE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3494	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3495	OCTYLBICYCLOHEPTENEDICARBOXIMIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (OBCARB) 'Contains octylbicycloheptenedicarboximide' (or words to that effect).
3496	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3497	OCTYLDODECETH-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			level of detection.
3498	OCTYLDODECYL CITRATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 12%.
3499	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3500	OCTYLDODECYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3501	OENANTHATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3502	OENANTHE AQUATICA	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3503	OENANTHE CROCATA	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3504	OENOTHERA BIENNIS	A,E,H	
3505	OENOTHERA STRICTA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3506	OKOUBAKA AUBREVILLEI	A,H	
3507	OLDENLANDIA DIFFUSA	A,E,H	
3508	OLEA EUROPAEA	A,E,H	
3509	OLEIC ACID	E	
3510	OLETH-10	E	Only for use in topical medicines for dermal application.
3511	OLETH-2	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of Oleth-2. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3512	OLETH-20	E	Only for use in topical medicines for dermal application.
3513	OLETH-3	E	Only for use in topical medicines for dermal application.
3514	OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.12%.
3515	OLETH-5	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3516	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3517	OLIBANUM OIL	A,E,H	
3518	OLIGOFRUCTOSE	A,E	
3519	OLIVE	E	
3520	OLIVE OIL	A,E,H	
3521	OMEGA-3-ACID ETHYL ESTERS 90	A	Only for use in oral medicines. The maximum recommended daily dose must not exceed 4000 mg of Omega-3-acid ethyl esters 90, AND must not provide more than 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids. The medicine requires the following warning statements on the medicine label: -'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect). -'To be taken with food' (or words to that effect). - 'Not recommended for used by pregnant and lactating women' (or words to that effect). - 'Use in children under 12 years is not recommended' (or words to that effect).
3522	OMEGA-3 FISH OIL	A	The medicine requires the following warning statements on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	PHYTOSTEROL ESTERS		label: - (VOPE) 'There is no benefit from taking more than 3g/day of phytosterols from all sources' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
3523	ONION	E	
3524	ONION OIL	A,H	
3525	ONONIS SPINOSA	A,E,H	
3526	ONOPORDON ACANTHIUM	A,H	
3527	ONOSMODIUM VIRGINIANUM	A,H	
3528	OPHIOPOGON JAPONICUS	A,H	
3529	OPOPANAX CHIRONIUM	A,H	
3530	OPOPANAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3531	OPUNTIA FICUS-INDICA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3532	ORANGE	E	
3533	ORANGE FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3534	ORANGE FLOWER OIL	A,E,H	When used internally, oxedrine is a mandatory component of orange flower oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3535	ORANGE JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3536	ORANGE JUICE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3537	ORANGE OIL	A,E,H	When used internally, oxedrine is a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			mandatory component of orange oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3538	ORANGE OIL BITTER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3539	ORANGE OIL BITTER COLDPRESSED	A,E,H	When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
3540	ORANGE OIL COLD PRESSED	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3541	ORANGE OIL DISTILLED	A,E,H	When used internally, oxedrine is a mandatory component of orange oil distilled. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3542	ORANGE OIL SWEET	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3543	ORANGE OIL TERPENELESS	A,E,H	When used internally, oxedrine is a mandatory component of orange oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3544	ORANGE PEEL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
3545	ORANGE PEEL DRIED BITTER	A,E,H	When used internally, oxedrine is a mandatory component of orange peel dried bitter. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3546	ORANGE PEEL OIL SWEET TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3547	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3548	OREODAPHNE CALIFORNICA	A,H	
3549	ORIGANUM MAJORANA	A,H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 50 millilitres. When the concentration of Origanum majorana oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			children' (or words to that effect)
3550	ORIGANUM OIL	E	Permitted for use only in combination with other ingredients as a fragrance. If used as a fragrance the total concentration in the medicine must be no more than 1%.
3551	ORIGANUM OIL SPANISH	A,E,H	
3552	ORIGANUM VULGARE	A,E,H	
3553	ORNITHINE	A,E	
3554	ORNITHINE ASPARTATE	A,E	
3555	ORNITHINE MONOHYDROCHLORIDE	A,E	
3556	ORNITHOGALUM UMBELLATUM	A,H	
3557	OROSTACHYS FIMBRIATA	A,H	
3558	OROXYLUM INDICUM	A,H	
3559	ORRIS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3560	ORRIS CONCRETE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
3561	ORRIS ROOT EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3562	ORRIS ROOT OIL	A,E,H	
3563	ORRIS ROOT RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3564	ORTHO-CYMEN-5-OL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3565	ORTHO-TERT-BUTYLCYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3566	ORTHOSIPHON ARISTATUS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3567	ORYZA SATIVA	A,E,H	
3568	ORYZANOL	E	
3569	OSBECKIA CHINENSIS	A,H	
3570	OSMANTHUS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3571	OSMANTHUS FRAGRANS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3572	OTTELIA ALISMOIDES	A,H	
3573	OXACYCLOHEPTADEC-11-EN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3574	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3575	OXACYCLOHEXADECEN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3576	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3577	OXALIS ACETOSELLA	A,H	
3578	OXIDISED MAIZE STARCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3579	OXIDISED TAPIOCA STARCH	E	
3580	OXYBENZONE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
3581	OYSTER	E	
3582	OYSTER SHELL	A,E,H	

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3583	P-ALPHA-DIMETHYL STYRENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3584	P-ANISIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
3585	PADIMATE O	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 8%.
3586	PADINA PAVONICA THALLUS	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	PHYTOSTEROLS		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
3587	PAEONIA LACTIFLORA	A,E,H	
3588	PAEONIA OBOVATA	A,H	
3589	PAEONIA SUFFRUTICOSA	A,E,H	
3590	PAEONIA VEITCHII	A,H	
3591	PALIURUS SPINA-CHRISTI	A,H	
3592	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3593	PALM FRUIT OIL	A,E,H	
3594	PALM GLYCERIDES	E	
3595	PALM KERNEL OIL	A,E,H	
3596	PALM TOCOTRIENOLS COMPLEX	A,H	
3597	PALMAROSA OIL	A,E,H	
3598	PALMITIC ACID	E	
3599	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3600	PALMITOYL DIPEPTIDE-7	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 0.002%.
3601	PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%
3602	PALMITOYL OLIGOPEPTIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.
3603	PALMITOYL PENTAPEPTIDE-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
3604	PALMITOYL TETRAPEPTIDE-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.001%.
3605	PANAX GINSENG	A,E,H	
3606	PANAX JAPONICUS	A,H	
3607	PANAX NOTOGINSENG	A,H	
3608	PANAX PSEUDOGINSENG	A,H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3609	PANAX QUINQUEFOLIUS	A,H	
3610	PANICUM MILIACEUM	A,H	
3611	PANTETHINE	E	Only for use in topical medicines for dermal application.
3612	PANTHENOL	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3613	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3614	PANTOLACTONE	E	
3615	PANTOTHENIC ACID	A,E	When used topically, the concentration in the medicine must be no more than 0.1%.
3616	PANTOTHENIC ACID POLYPEPTIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3617	PAPAIN	A,E	
3618	PAPER	E	Only for use in topical medicines for dermal application.
3619	PAPRIKA OLEORESIN	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3620	PARA-CRESOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3621	PARA-CRESYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3622	PARA-CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3623	PARA-CRESYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3624	PARA-CYMENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3625	PARA-ETHOXYBENZALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3626	PARA-HYDROXY BENZALACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3627	PARA-HYDROXYBENZOIC ACID	E	
3628	PARA-MENTHA-8-THIOL-3-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3629	PARA-METHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3630	PARA-METHYL ANISOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3631	PARA-METHYL DIMETHYLBENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3632	PARA-PROPYL ANISOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
3633	PARA-TERT-BUTYLCYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3634	PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3635	PARA-TOLUALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3636	PARA-TOLYL ACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3637	PARAMERIA LAEVIGATA	A,H	
3638	PARIETARIA JUDAICA	A,H	
3639	PARIS POLYPHYLLA	A,H	
3640	PARIS QUADRIFOLIA	A,H	
3641	PARSLEY	E,H	
3642	PARSLEY HERB DRY	A,E,H	
3643	PARSLEY HERB OIL	A,E,H	
3644	PARSLEY HERB POWDER	A,E,H	
3645	PARSLEY SEED OIL	A,E,H	
3646	PARTHENOCISSUS TRICUSPIDATA	A,H	
3647	PARTIALLY HYDROGENATED SOYA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
3648	PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00002%.
3649	PASPALUM NOTATUM	A,H	
3650	PASSIFLORA CAERULEA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3651	PASSIFLORA EDULIS	E	
3652	PASSIFLORA HERB DRY	A,H	
3653	PASSIFLORA INCARNATA	A,E,H	
3654	PATCHOULI OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3655	PATENT BLUE V	E	Permitted for use as a colour for oral and topical use.
3656	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
3657	PATRINIA SCABIOSIFOLIA	A,H	
3658	PATRINIA VILLOSA	A,H	
3659	PAULLINIA CUPANA	A,E,H	Caffeine is a mandatory component of Paullinia cupana when used for oral ingestion. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
3660	PAULLINIA PINNATA	A,H	
3661	PAWPAW	E	
3662	PEA	E	
3663	PEA STARCH	E	
3664	PEACH	E	
3665	PEANUT	E	The medicine requires the following warning statement on the medicine label: - (PEANUT) 'Contains [insert ingredient name]'.
3666	PEAR	E	
3667	PECAN	E	
3668	PECTIN	A,E	
3669	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3670	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3671	PEG-12 DILAURATE	E	
3672	PEG-12 DIMETICONE/PPG-20 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3673	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3674	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3675	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3676	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3677	PEG-20 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3678	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3679	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3680	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3681	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3682	PEG-25 PABA	A	Only for use as an active ingredient in topical sunscreens for dermal application. The concentration in the medicine must be no more than 10%.
3683	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3684	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3685	PEG-35 CASTOR OIL	E	
3686	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3687	PEG-4 LAURATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3688	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3689	PEG-40 CASTOR OIL	E	
3690	PEG-40 HYDROGENATED CASTOR OIL	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3691	PEG-40 SORBITAN DIISOSTEARATE	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3692	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3693	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3694	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3695	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3696	PEG-55 PROPYLENE GLYCOL OLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.6%.
3697	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3698	PEG-60 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration when used in

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicines applied directly to the skin must be no more than 10%. The concentration when used in bath oil medicines must be no more than 30%.
3699	PEG-60 GLYCERYL ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3700	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3701	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3702	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3703	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3704	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3705	PEG-75 STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3706	PEG-8 CETYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 0.0005%.
3707	PEG-8 DILAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
3708	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3709	PEG-8 LAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.
3710	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3711	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3712	PEG/PPG-18/18 DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3713	PELARGONIUM GRAVEOLENS	A,E,H	
3714	PELLITORINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3715	PELTIGERA CANINA	A,H	
3716	PENICILLIUM EXPANSUM	A,H	
3717	PENNYROYAL OIL	E	D-Pulegone/Pulegone is a mandatory component of Pennyroyal Oil. The concentration of D Pulegone/ Pulegone in the medicine must be no more than 4%. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in the medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Pennyroyal Oil.
3718	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	NAMATE		use in the eye. The concentration in the medicine must be no more than 0.018%
3719	PENTAERYTHRITYL TETRAISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 61%.
3720	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3721	PENTAMETHYLHEPTENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3722	PENTANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3723	PENTASODIUM ETHYLENEDIAMINE TETRAMETHYLENE PHOSPHONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.1%.
3724	PENTYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3725	PEPPER BLACK	E,H	
3726	PEPPER OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3727	PEPPER WHITE	E,H	
3728	PEPPERMINT AMERICAN EXT.	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3729	PEPPERMINT LEAF DRY	A,E,H	
3730	PEPPERMINT LEAF POWDER	A,E,H	
3731	PEPPERMINT OIL	A,E,H	
3732	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3733	PEPPERMINT TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3734	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3735	PERHYDRO-3,6-DIMETHYL-BENZO [B] FURAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3736	PERILLA FRUTESCENS	A,E,H	Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of Perilla frutescens is leaf.
3737	PERILLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
3738	PERLITE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3739	PERMETHRIN	E	The concentration of in the medicine must be no more than 2%.
3740	PERSEA AMERICANA	A,E,H	
3741	PERSIC OIL	A,E,H	Amygdalin and Hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must be no more than 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
3742	PERSICARIA CHINENSIS	A,H	
3743	PERSICARIA TINCTORIA	A,H	
3744	PERSIMMON	E	
3745	PERU BALSAM	A,E,H	
3746	PERU BALSAM OIL	A,E,H	
3747	PETITGRAIN MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The final concentration of the oil in the flavour does not exceed 30% If used in a flavour the total flavour concentration in a medicine must be no more than 5%
3748	PETITGRAIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3749	PETITGRAIN OIL PARAGUAY	A,E,H	When used internally, oxedrine is a mandatory component of petitgrain oil paraguay. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3750	PETITGRAIN OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3751	PETROSELINUM CRISPUM	A,E,H	
3752	PEUCEDANUM	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	PRAERUPTORUM		
3753	PEUMUS BOLDUS	A,H	Volatile oil components (of Peumus boldus) is a mandatory component. The maximum recommended daily dose must be no more than 100 mg of volatile oil components (of Peumus boldus).
3754	PHALARIS ARUNDINACEA	A,H	
3755	PHALARIS CANARIENSIS	A,H	
3756	PHASEOLUS COCCINEUS	A,H	
3757	PHASEOLUS VULGARIS	A,H	
3758	PHELLINUS ROBINIAE	A,E,H	
3759	PHELLODENDRON AMURENSE	A,E,H	
3760	PHELLODENDRON CHINENSE	A,H	
3761	PHENACETIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
3762	PHENETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3763	PHENETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3764	PHENETHYL ALCOHOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PHEALC) 'Contains phenethyl alcohol' (or words to that effect).
3765	PHENETHYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3766	PHENETHYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%
3767	PHENETHYL ISOAMYL	E	Permitted for use only in combination

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ETHER		with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3768	PHENETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3769	PHENETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3770	PHENETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3771	PHENETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3772	PHENOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PHENOL) 'Contains phenol' (or words to that effect). The concentration of phenols in the medicine including cresols and xylenols and any other homologue of phenol boiling below 220 degrees centigrade must be no more than 3%.
3773	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PHOETH) 'Contains phenoxyethanol' (or words to that effect).
3774	PHENOXYETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3775	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3776	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3777	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3778	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3779	PHENYLACETALDEHYDE DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3780	PHENYLACETALDEHYDE GLYCERYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3781	PHENYLACETIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3782	PHENYLALANINE	A,E	When for oral ingestion the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect). When the medicine contains more than 500mg in the maximum recommended daily dose it requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.
3783	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 4%.
3784	PHENYLETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3785	PHENYLETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3786	PHENYLETHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3787	PHENYLETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3788	PHENYLETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3789	PHENYLETHYL METHYLETHYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3790	PHENYLETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3791	PHENYLETHYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3792	PHENYLISOPROPYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 5%.
3793	PHENYLPROPANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.16%.
3794	PHLEUM PRATENSE	A,H	
3795	PHLOXINE B	E	Permitted for use as a colour for oral and topical use.
3796	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
3797	PHOENIX DACTYLIFERA	A,E,H	
3798	PHOSPHATIDYL CHOLINE	E	
3799	PHOSPHOLIPIDS	E	Only for use in topical medicines for dermal application and not intended for use in the eye. The concentration in the medicine must be no more than 20%.
3800	PHOSPHORIC ACID	E,H	Only for use as an active homoeopathic ingredient. The concentration in liquid medicines must be no more than 15%.
3801	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.
3802	PHOTINIA SERRULATA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3803	PHRAGMITES AUSTRALIS	A,H	
3804	PHYLA DULCIS	A,H	
3805	PHYLLANTHUS AMARUS	A,H	
3806	PHYLLANTHUS EMBLICA	A,E,H	Only for use in topical medicines for dermal application. When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3807	PHYLLOSTACHYS NIGRA	A,E,H	
3808	PHYSALIS ALKEKENGI	A,H	
3809	PHYSALIS PUBESCENS	A,H	
3810	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3811	PHYTOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3812	PHYTOLACCA AMERICANA	A,H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3813	PHYTOMENADIONE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
3814	PHYTOSPHINGOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3815	PHYTOSTERYL/OCTYL DODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3816	PICEA ABIES	A,H	
3817	PICEA MARIANA	A,H	
3818	PICRASMA EXCELSA	A,E,H	
3819	PICRORRHIZA KURROA	A,E,H	
3820	PIGMENT BLUE 15	E	Permitted for use as a colour for topical and dental use. The concentration in medicine must be no more than 0.003%.
3821	PIGMENT BLUE 15:1	E	Permitted for use as a colour for topical use. Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.21%.
3822	PIGMENT GREEN 7	E	When for dental use, the concentration in the medicine must be no more than 0.003%. When for topical use, the concentration in the medicine must be no more than 0.17%. Permitted for use as a colour for topical and dental use.
3823	PIGMENT RED 4	E	Permitted for use as a colour for topical use.
3824	PIGMENT RED 53	E	Permitted for use as a colour for topical use.
3825	PIGMENT RED 57	E	Permitted for use as a colour for topical use.
3826	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use as a colour for topical use.
3827	PIGMENT RED 63	E	Permitted for use as a colour for topical use.
3828	PIGMENT WHITE 26	E	Permitted for use as a colour for topical use.
3829	PIGMENT YELLOW 12	E	Permitted for use as a colour for topical use.
3830	PILOCARPUS JABORANDI	A,H	Pilocarpine is a mandatory component of Pilocarpus jaborandi. The concentration of pilocarpine in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			0.025%.
3831	PILOCARPUS MICROPHYLLUS	A,H	Pilocarpine is a mandatory component of Pilocarpus microphyllus. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3832	PILOCARPUS PINNATIFOLIUS	A,H	Pilocarpine is a mandatory component of Pilocarpus pinnatifolius. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3833	PIMENTA FRUIT OIL	A,E,H	
3834	PIMENTA LEAF OIL	A,E,H	
3835	PIMENTA OFFICINALIS	A,E,H	
3836	PIMENTA RACEMOSA	A,E,H	When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'.
3837	PIMPINELLA ANISUM	A,E,H	When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%: a) the nominal capacity of the container must be no more than 50 millilitres; and b) a restricted flow insert is must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or words to that effect).
3838	PIMPINELLA SAXIFRAGA	A,E,H	
3839	PINE NEEDLE OIL SCOTCH	A,E,H	
3840	PINE NEEDLE OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3841	PINE OIL AROMATIC	A,E,H	
3842	PINE OIL PUMILIO	A,E,H	
3843	PINEAPPLE	E	
3844	PINEAPPLE OILS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3845	PINELLIA TERNATA	A,H	
3846	PINUS CONTORTA	A,E,H	
3847	PINUS ELLIOTTII	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5% If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3848	PINUS MASSONIANA	A,E,H	When the plant preparation is oil or distillate the total concentration of Pinus massoniana oil or distillate in the preparation must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			25%.
3849	PINUS MONTICOLA	A,E,H	
3850	PINUS MUGO	A,E,H	
3851	PINUS PALUSTRIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3852	PINUS PINASTER	A,E,H	When the plant preparation is oil or distillate the total concentration of Pinus pinaster oil or distillate in the preparation must be no more than 25%.
3853	PINUS PONDEROSA	A,E,H	
3854	PINUS RADIATA	A,E,H	
3855	PINUS STROBUS	A,E,H	
3856	PINUS SYLVESTRIS	A,E,H	
3857	PINUS TABULIFORMIS	A,E,H	
3858	PINUS YUNNANENSIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3859	PIPENZOLATE BROMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
3860	PIPER CHABA	A,E,H	
3861	PIPER CUBEBA	A,E,H	
3862	PIPER EXCELSUM VAR. MAJOR	A,H	
3863	PIPER KADSURA	A,E,H	
3864	PIPER LONGUM	A,E,H	
3865	PIPER METHYSTICUM	A,H	Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum. When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg. If the dosage form is tablet or capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule. Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label: - (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver.' The plant part must be root or rhizome. When for oral use, the plant

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			preparation must be an aqueous dispersion or aqueous extract of dried whole or peeled root or rhizome. When for topical use on the rectum, vagina or throat, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome. When the container type is tea bag the maximum quantity per tea bag must be no more than 3 grams of dried whole or peeled root or rhizomes.
3866	PIPER NIGRUM	A,E,H	
3867	PIPER SARMENTOSUM	A,E,H	
3868	PIPERIDINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3869	PIPERITONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3870	PIPERONAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3871	PIPERONYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used as a flavour the total flavour concentration in a medicine must be no more than 5%. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3872	PIPERONYL BUTOXIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect).
3873	PIROCTONE OLAMINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3874	PISCIDIA PISCIPULA	A,E,H	
3875	PISTACIA LENTISCUS	A,E,H	
3876	PISUM SATIVUM	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3877	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3878	PLANTAGO AFRA	A,E,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3879	PLANTAGO ARENARIA	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3880	PLANTAGO ASIATICA	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3881	PLANTAGO LANCEOLATA	A,E,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3882	PLANTAGO MAJOR	A,E,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3883	PLANTAGO OVATA	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3884	PLANTAGO SEED DRY	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3885	PLATANUS OCCIDENTALIS	A,E,H	
3886	PLATANUS RACEMOSA	A,H	
3887	PLATANUS X ACERIFOLIA	A,H	
3888	PLATYCODON GRANDIFLORUS	A,E,H	
3889	PLICATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3890	PLUM	E	
3891	PLUMBAGO EUROPAEA	A,H	
3892	PLUMERIA ALBA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3893	PLUMERIA RUBRA	A,E,H	
3894	POA NEMORALIS	A,H	
3895	POA PRATENSIS	A,H	
3896	PODOPHYLLUM PELTATUM	A,H	Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum. The concentration of podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%. The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3897	POGOSTEMON CABLIN	A,E,H	
3898	POLACRILIN	E	
3899	POLACRILIN POTASSIUM	E	
3900	POLAPREZINC	A	Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc. The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).
3901	POLIGLUSAM	A,E	When used orally, the medicine requires the following warning statements on the medicine label: - (CHITO) 'Chitosan should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect) AND (for powdered dosage forms only) 'Do not take powder alone. Mix with food or fluid.' - (SFOOD) 'Derived from seafood'. When used as an excipient, only for use in topical medicines for dermal application.
3902	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A,E	When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from Aspergillus niger per maximum recommended daily dose and requires the following warning statement on the medicine label: - (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			effect). If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the medicine label: - 'Do not take powder alone. Mix with food or fluid.' When used as an excipient, Poliglusam derived from Aspergillus niger is only permitted for use in topical medicines for dermal application.
3903	POLLACK-LIVER OIL	A,E	Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			balanced diet.' The indication 'Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life' is permitted only for oral use.
3904	POLLEN	E	The medicine requires the following warning statement on the medicine label: - (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).
3905	POLOXAMER	E	Only for use in topical medicines for dermal application.
3906	POLOXAMINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3907	POLOXAMINE 1301	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3908	POLY C10-30 ALKYL ACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3909	POLYACRYLAMIDE	E	Only for use in topical medicines for dermal application. Acrylamide is a mandatory component of Polyacrylamide. The concentration of Acrylamide in the medicine must be no more than 0.01%.
3910	POLYACRYLATE-1 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.4%.
3911	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3912	POLYACRYLIC ACID	E	
3913	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3914	POLYAMINOPROPYL BIGUANIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3915	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3916	POLYBUTYLENE GLYCOL/PPG-9/1	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	COPOLYMER		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3917	POLYCAPROLACTONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3918	POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3919	POLYDEXTROSE	E	
3920	POLYDIETHYLSILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3921	POLYDIMETHYL SILOXANE	E	Permitted for use only in combination with other permitted ingredients as a printing ink. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
3922	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 1.5%.
3923	POLYESTER-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
3924	POLYESTER-7	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3925	POLYESTER-8	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration of Polyester-8 must be no more than 5%.
3926	POLYETHYLENE	E	
3927	POLYGALA CHINENSIS	A,H	
3928	POLYGALA SENEGA	A,E,H	Except when used in a medicine containing only homoeopathic preparations, a child resistant closure and restricted flow insert must be fitted onto the container.
3929	POLYGALA SIBIRICA	A,E,H	Only for use when the plant part is root or root bark.
3930	POLYGALA	A	Only for use when the plant part is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TENUIFOLIA		root or root bark.
3931	POLYGLYCERYL-10 PENTASTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3932	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3933	POLYGLYCERYL-2 DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3.0%.
3934	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3935	POLYGLYCERYL-2 TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
3936	POLYGLYCERYL-3 BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3937	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3938	POLYGLYCERYL-3 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3939	POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3940	POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5.5%.
3941	POLYGLYCERYL-3 POLYRICINOLEATE	E	
3942	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIMER DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3943	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 3%.
3944	POLYGLYCERYL-4 ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3945	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
3946	POLYGLYCERYL-6 POLYRICINOLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3947	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
3948	POLYGONATUM MULTIFLORUM	A,H	
3949	POLYGONATUM OFFICINALE	A,H	
3950	POLYGONATUM SIBIRICUM	A,E,H	
3951	POLYGONUM AVICULARE	A,E,H	When used as an excipient, the medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			0.16%.
3952	POLYGONUM BISTORTA	A,H	
3953	POLYGONUM CUSPIDATUM	A,E,H	
3954	POLYGONUM ODORATUM	A,H	
3955	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
3956	POLYISOBUTYLENE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Polyisobutylene monograph in the Food Chemicals Codex published by the United States Pharmacopeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopeia-National Formulary , as in force or existing from time to time.
3957	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
3958	POLYLIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3959	POLYMETHACRYLIC ACID	E	
3960	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
3961	POLYMETHYLSILSESQUIOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
3962	POLYPORUS UMBELLATUS	A,H	
3963	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
3964	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
3965	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
3966	POLYQUATERNIUM-22	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3967	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
3968	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
3969	POLYQUATERNIUM-37	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
3970	POLYQUATERNIUM-44	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3971	POLYQUATERNIUM-51	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3972	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
3973	POLYSILICONE-11	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.1%
3974	POLYSILICONE-14	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration of Polysilicone-14 must be no more than 1%.
3975	POLYSILICONE-15	A	Only for use as an active ingredient in sunscreens.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
3976	POLYSILICONE-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.13%.
3977	POLYSORBATE 20	E	
3978	POLYSORBATE 40	E	
3979	POLYSORBATE 60	E	
3980	POLYSORBATE 65	E	
3981	POLYSORBATE 80	E	
3982	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
3983	POLYTEF	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3984	POLYURETHANE-34	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			applications.
3985	POLYURETHANE-62	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3986	POLYVINYL ACETATE	E	Only for use when the dosage form is chewing gum.
3987	POLYVINYL ACETATE PHTHALATE	E	
3988	POLYVINYL ALCOHOL	E	
3989	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
3990	POMEGRANATE	E	
3991	PONCEAU SX	E	Permitted for use as a colour for topical use.
3992	PONCIRUS TRIFOLIATA	A,H	When used interally, oxedrine is a mandatory component of Poncirus trifoliata. The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
3993	PONGAMOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3994	POPPY SEED	E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
3995	POPPY SEED OIL	E,H	
3996	POPULUS ALBA	A,H	
3997	POPULUS BALSAMIIFERA	A,E,H	
3998	POPULUS CANDICANS	A,H	
3999	POPULUS DELTOIDES	A,H	
4000	POPULUS NIGRA	A,H	
4001	POPULUS TREMULA	A,H	
4002	POPULUS TREMULOIDES	A,H	
4003	PORCINE	H	Only for use as an active homoeopathic ingredient.
4004	PORIA COCOS	A,E,H	
4005	PORPHYRIDIUM PURPUREUM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4006	PORTULACA OLERACEA	A,E,H	
4007	POTABLE WATER	E	
4008	POTASSIUM ACETATE	E	
4009	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4010	POTASSIUM ASCORBATE	A,E,H	When for oral or sublingual use, potassium is a mandatory component

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of potassium ascorbate. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4011	POTASSIUM ASCORBATE DIHYDRATE	A,E,H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4012	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4013	POTASSIUM ASPARTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium aspartate. The percentage of Potassium from Potassium aspartate should be calculated based

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			on the molecular weight of Potassium aspartate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4014	POTASSIUM ASPARTATE DIHYDRATE	A,E,H	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate dihydrate. The percentage of potassium from potassium aspartate dihydrate should be calculated based on the molecular weight of potassium aspartate dihydrate.
4015	POTASSIUM ASPARTATE MONOHYDRATE	A,E	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate monohydrate. The percentage of potassium from potassium aspartate monohydrate should be calculated based on the molecular weight of potassium aspartate monohydrate.
4016	POTASSIUM BICARBONATE	E	
4017	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4018	POTASSIUM CARBONATE	E,H	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			preparation, the pH of the preparation must not exceed 11.5. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4019	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4020	POTASSIUM CHLORIDE	A,E,H	When for oral use: a) potassium is a mandatory component of potassium chloride; b) the medicine requires the following warning statement on the medicine label: - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit. Medicines for use as oral rehydration therapy, are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium, potassium and glucose

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and c) the medicine requires the warning statements: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must be no more than 3.75%.
4021	POTASSIUM CITRATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium citrate. The percentage of potassium from Potassium citrate should be calculated based on the molecular weight of Potassium citrate. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
4022	POTASSIUM COCOYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			use in the eye. The concentration in the medicine must be no more than 10%.
4023	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
4024	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4025	POTASSIUM GLUCONATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium gluconate. The percentage of potassium from Potassium gluconate should be calculated based on the molecular weight of Potassium gluconate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4026	POTASSIUM GLYCEROPHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium glycerophosphate. The percentage of Potassium from potassium glycerophosphate should be calculated based on the molecular weight of potassium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			glycerophosphate. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4027	POTASSIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4028	POTASSIUM HYDROXYCITRATE	A,H	The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4029	POTASSIUM IODATE	A,H	Iodine is a mandatory component of potassium iodate. The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate. When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate. When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.
4030	POTASSIUM IODIDE	A,E,H	Iodine is a mandatory component of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Potassium iodide. The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of potassium iodide. The percentage of potassium from potassium iodide should be calculated based on the molecular weight of potassium iodide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4031	POTASSIUM METABISULFITE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4032	POTASSIUM	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	METAPHOSPHATE		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4033	POTASSIUM NITRATE	A,H	Only for dental use. The concentration in the medicine must be no more than 5%.
4034	POTASSIUM OROTATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium orotate. The percentage of potassium from Potassium orotate should be calculated based on the molecular weight of Potassium orotate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4035	POTASSIUM PYROPHOSPHATE	E	Only for oral application, dental or topical use. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4036	POTASSIUM SORBATE	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4037	POTASSIUM STANNATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4038	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4039	POTASSIUM SULFATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium sulfate. The percentage of potassium from potassium sulfate should be calculated based on the molecular weight of potassium sulfate. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
4040	POTATO STARCH	E	
4041	POTENTILLA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	ANSERINA		
4042	POTENTILLA CHINENSIS	A,H	
4043	POTENTILLA DISCOLOR	A,H	
4044	POTENTILLA ERECTA	A,E,H	
4045	POTENTILLA REPTANS	A,H	
4046	POTERIUM OFFICINALE	A,E,H	
4047	POTERIUM SANGUISORBA	A,H	
4048	POVIDONE	E	
4049	POWDERED CELLULOSE	E	
4050	PPG-1-PEG-9 LAURYL GLYCOL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4051	PPG-12/SMDI COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4052	PPG-15 STEARYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.3%.
4053	PPG-15 STEARYL ETHER BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.4%.
4054	PPG-17/IPDI/DMPA COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of PPG-17/IPDI/DMPA Copolymer in the medicine must be no more than 10%.
4055	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4056	PPG-2 MYRISTYL ETHER PROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4057	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4058	PPG-20 METHYL GLUCOSE ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4059	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4060	PPG-3 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4061	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4062	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4063	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4064	PRALINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4065	PREGELATINISED MAIZE STARCH	E	
4066	PREGELATINISED POTATO STARCH	E	
4067	PREGELATINISED RICE STARCH	E	
4068	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of Pregelatinised wheat starch.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4069	PRENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4070	PRICKLY ASH BARK DRY	A,H	
4071	PRICKLY ASH BARK POWDER	A,H	
4072	PRIMULA VERIS	A,E,H	
4073	PRIMULA VULGARIS	A,E,H	
4074	PRINSEPIA UNIFLORA	A,H	
4075	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4076	PROLINE	A,E	
4077	PROPAN-1-OL	E	Only for use in topical medicines for dermal application. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			must be no more than 18%.
4078	PROPANE	E	Only for use as an excipient propellant ingredient.
4079	PROPENYL GUAETHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4080	PROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4081	PROPIONIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4082	PROPIONYLLEVOCARNITINE	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HYDROCHLORIDE		
4083	PROPOLIS	A,E	Lead is a mandatory component of Propolis. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4084	PROPOLIS BALSAM	A,E	Lead is a mandatory component of Propolis balsam. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4085	PROPOLIS DRY EXTRACT	A,E	Lead is a mandatory component of Propolis dry extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4086	PROPOLIS LIQUID EXTRACT	A,E	Lead is a mandatory component of Propolis liquid extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4087	PROPOLIS RESIN	A,E	Lead is a mandatory component of propolis resin. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4088	PROPOLIS TINCTURE	A,E	Lead is a mandatory component of Propolis tincture. The concentration of lead in the medicine must be no more than 0.001%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4089	PROPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4090	PROPYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4091	PROPYL GALLATE	E	
4092	PROPYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4093	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4094	PROPYLENE GLYCOL	E	
4095	PROPYLENE GLYCOL ALGINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4096	PROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 20%.
4097	PROPYLENE GLYCOL DIDECANOATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4098	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4099	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4100	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4101	PROPYLENE GLYCOL ISOCETETH-3 ACETATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4102	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4103	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4104	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4105	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4106	PROSOPIS JULIFLORA	A,H	
4107	PROTEASE	A	Must be derived from Aspergillus oryzae. When the dosage form is undivded, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted. When the dosage form is divded, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4108	PROTEIN HYDROLYSATE	E	
4109	PRUNE JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4110	PRUNE JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4111	PRUNELLA VULGARIS	A,H	
4112	PRUNUS AFRICANA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4113	PRUNUS ARMENIACA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4114	PRUNUS AVIUM	A,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4115	PRUNUS CERASIFERA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4116	PRUNUS CERASUS	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4117	PRUNUS DOMESTICA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4118	PRUNUS DULCIS	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed. When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4119	PRUNUS HUMILIS	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4120	PRUNUS JAPONICA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. The concentration of Amygdalin in

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4121	PRUNUS LAUROCERASUS	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4122	PRUNUS MUME	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4123	PRUNUS PERSICA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4124	PRUNUS SALICINA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4125	PRUNUS SEROTINA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4126	PRUNUS SPINOSA	A,E,H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4127	PRUSSIAN BLUE	E	Permitted for use as a colour for topical use.
4128	PSEUDOCYDONIA SINENSIS	A,H	
4129	PSEUDOSTELLARIA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HETEROPHYLLA		
4130	PSEUDOTSUGA MENZIESII	A,H	
4131	PSEUDOWINTERA COLORATA	A,H	Only for use when the plant part is leaf.
4132	PSIDIUM GUAJAVA	A,E,H	
4133	PSORALEN (OF CULLEN CORYLIFOLIUM)	E	
4134	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4135	PSYLLIUM HUSK DRY	A,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4136	PSYLLIUM HUSK POWDER	A,E,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4137	PSYLLIUM SEED DRY	A,E,H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4138	PTELEA TRIFOLIATA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4139	PTEROCARPUS MARSUPIUM	A,H	
4140	PTEROCARPUS SANTALINUS	A,E,H	
4141	PUERARIA LOBATA	A,E,H	
4142	PUERARIA MONTANA VAR. LOBATA	A,E,H	
4143	PULLULAN	E	
4144	PUMICE	E	
4145	PUMPKIN	E	
4146	PUMPKIN SEED	E,H	
4147	PUMPKIN SEED OIL	E,H	
4148	PUNICA GRANATUM	A,E,H	
4149	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4150	PURIFIED HONEY	A,E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect). When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
4151	PURIFIED SILICEOUS EARTH	E,H	Only for use as an active homoeopathic or excipient ingredient.
4152	PURIFIED TALC	E	
4153	PURIFIED WATER	E	
4154	PVM/MA COPOLYMER	E	
4155	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4156	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4157	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4158	PYRETHRINS	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%. The medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (PYRTH3) 'Contains pyrethrins' (or words to that effect).
4159	PYRIDOXAL 5-PHOSPHATE	A,E	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate. The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6]'. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4160	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	Pyridoxine is a mandatory component of Pyridoxal 5-phosphate monohydrate. The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6]'. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’
4161	PYRIDOXINE	A,E,H	When not used as an active homoeopathic ingredient, pyridoxine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HYDROCHLORIDE		is a mandatory component of Pyridoxine hydrochloride. The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride. The maximum recommended daily dose must provide no more than 200 mg of pyridoxine. If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6]'. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’
4162	PYROGLUTAMIC ACID	E	
4163	PYROLA DECORATA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4164	PYROLIGNEOUS ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4165	PYRROSIA LINGUA	A,H	
4166	PYRROSIA PETIOLOSA	A,H	
4167	PYRROSIA SHEARERI	A,H	
4168	PYRUS COMMUNIS	A,E,H	
4169	PYRUS PYRIFOLIA	A,H	
4170	PYRUVIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4171	QUASSIA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4172	QUASSIA AMARA	A,E,H	
4173	QUASSIA WOOD JAMAICAN DRY	A,H	
4174	QUASSIA WOOD JAMAICAN POWDER	A,H	
4175	QUATERNIUM-15	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application. The medicinerequires the following warning statement on the medicine label: - (QUAT15) 'Contains quaternium-15' (or words to that effect).
4176	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4177	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4178	QUATERNIUM-52	E	Only for use in wash-on/wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. Not be used in medicines in which N-nitroso compounds may be formed.
4179	QUATERNIUM-80	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4180	QUERCETIN	A	
4181	QUERCETIN DIHYDRATE	A	
4182	QUERCUS ACUTISSIMA	A,H	
4183	QUERCUS ALBA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4184	QUERCUS PALUSTRIS	A,H	
4185	QUERCUS ROBUR	A,H	
4186	QUERCUS RUBRA	A,H	
4187	QUERCUS VIRGINIANA	A,H	
4188	QUILLAIA DRY	A,H	
4189	QUILLAIA POWDER	A,E,H	
4190	QUILLAJA SAPONARIA	A,H	
4191	QUINCE	E	
4192	QUININE ARSENITE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of Quinine arsenite. The maximum recommended daily dose must be no more than 50 mg of quinine.
4193	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of quinine sulfate dihydrate. The maximum recommended daily dose must be no more than 50 mg of quinine.
4194	QUINOLINE YELLOW	E	Permitted for use as a colour for oral and topical use.
4195	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
4196	QUISQUALIS INDICA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4197	R-ALPHA LIPOIC ACID	A	
4198	RACEMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4199	RACEMIC CAMPHOR	E,H	Only for use as an active homoeopathic or excipient ingredient. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
4200	RADISH	E,H	Only for use as an active homoeopathic or excipient ingredient.
4201	RAISIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4202	RAISIN JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4203	RANUNCULUS BULBOSUS	A,H	
4204	RANUNCULUS FICARIA	A,H	
4205	RANUNCULUS TERNATUS	A,H	
4206	RAPE OIL/TUNG OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4207	RAPE SEED OIL	A,E,H	Allyl isothiocyanate is a mandatory component of Rape seed oil. The maximum daily dose must not provide more than 20 mg of allyl isothiocyanate.
4208	RAPHANUS SATIVUS	A,H	
4209	RASPBERRY	E	
4210	RASPBERRY BRANDY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4211	RASPBERRY	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	DISTILLATE		flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4212	RASPBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4213	RASPBERRY JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4214	RAUWOLFIA SERPENTINA	A,H	The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4215	RAUWOLFIA SERPENTINA DRY	A,H	The concentration of Rauwolfia Serpentina Dry in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4216	RAUWOLFIA SERPENTINA POWDER	A,H	The concentration of Rauwolfia Serpentina Powder in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4217	RED 27	E	Permitted for use as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4218	RED 27 ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.
4219	RED ANT	H	Only for use as an active homoeopathic ingredient.
4220	RED CLOVER FLOWER DRY	A,H	
4221	RED CLOVER FLOWER POWDER	A,H	
4222	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4223	RED DEER	A	
4224	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4225	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4226	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4227	REHMANNIA GLUTINOSA	A,E,H	
4228	REL-1-((1R,2S)-1,2,3,4,5,6,7,8-OCTAHYDRO-1,2,8,8-TETRAMETHYL-2-NAPHTHALENYL)-1-ETHANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4229	RESORCINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4230	RESORCINOL DIMETHYLETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4231	RETINOL	A,E	Vitamin A is a mandatory component of retinol. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4232	RETINOL ACETATE	A,E	Vitamin A is a mandatory component of retinol acetate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4233	RETINOL PALMITATE	A,E	Vitamin A is a mandatory component of retinol palmitate. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4234	RHAMNOSE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4235	RHAMNUS CATHARTICA	A,H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) ‘If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) ‘Drink plenty of water' (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4236	RHAMNUS FRANGULA	A,H	Glucofrangulins calculated as glucofrangulin A is a mandatory component of Rhamnus frangula. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4237	RHATANY ROOT DRY	A,H	
4238	RHATANY ROOT POWDER	A,H	
4239	RHEUM OFFICINALE	A,E,H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4240	RHEUM PALMATUM	A,E,H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum palmatum. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4241	RHEUM RHAPONTICUM	A,E,H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum rhaponticum. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4242	RHEUM TANGUTICUM	A,H	The plant part must not be leaf. When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum rhaponticum.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4243	RHODAMINE B	E	Permitted for use as a colour for topical use.
4244	RHODINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4245	RHODINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4246	RHODIOLA ROSEA	A	Only for use in oral medicines. Only available for use when the plant preparation is dry root powder, dry root powder as an aqueous extract or dry root powder as a hydroethanolic extract with no more than 70% ethanol v/v.
4247	RHODODENDRON AUREUM	A,H	
4248	RHODODENDRON FERRUGINEUM	A,H	
4249	RHODODENDRON MOLLE	A,H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4250	RHODYMENIA PALMATA	A,H	
4251	RHUBARB	E,H	Only for use as an active homoeopathic or excipient ingredent. When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4252	RHUBARB ROOT DRY	A,H	When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rhubarb Root Dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4253	RHUBARB ROOT POWDER	A,H	When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rhubarb Root Powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4254	RHUS AROMATICA	A,E,H	
4255	RHUS CHINENSIS	A,H	
4256	RHUS GLABRA	A,E,H	
4257	RHUS VENENATA	H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			homoeopathic ingredient.
4258	RIBES GROSSULARIA	A,E,H	
4259	RIBES NIGRUM	A,E,H	
4260	RIBOFLAVIN	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4261	RIBOFLAVIN SODIUM PHOSPHATE	A,E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4262	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4263	RIBOFLAVINE	A,E	
4264	RIBOFLAVINE SODIUM PHOSPHATE	A,E	
4265	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4266	RIBOSE	A	Only for use in oral medicines. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4267	RICE	E	
4268	RICE BRAN	E	
4269	RICE BRAN OIL	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4270	RICE BRAN WAX	A,E,H	
4271	RICE STARCH	E	
4272	RICE VINEGAR	E	
4273	RICE WINE	E	Ethanol is a mandatory component of Rice wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
4274	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4275	RICINUS COMMUNIS	A,H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4276	ROBINIA PSEUDOACACIA	A,E,H	When the herbal substance is derived from plant parts other than the leaf or flower, the maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4277	ROHDEA JAPONICA	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4278	ROSA ARVENSIS	A,E,H	
4279	ROSA CANINA	A,E,H	
4280	ROSA CYMOSA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4281	ROSA EGLANTERIA	A,E,H	
4282	ROSA GALLICA	A,E,H	
4283	ROSA LAEVIGATA	A,E,H	
4284	ROSA MULTIFLORA	A,E,H	
4285	ROSA ROXBURGHII FRUIT EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.
4286	ROSA RUGOSA	A,E,H	
4287	ROSA VILLOSA	A,E,H	
4288	ROSA X CENTIFOLIA	A,E,H	
4289	ROSA X DAMASCENA	A,E,H	
4290	ROSANA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4291	ROSE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4292	ROSE FRUIT FRESH	A,E,H	
4293	ROSE HIP	E	
4294	ROSE OIL	A,E,H	
4295	ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4296	ROSEMARY OIL	A,E,H	Safrole is a mandatory component of Rosemary oil. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
4297	ROSMARINUS OFFICINALIS	A,E,H	Camphor and cineole are mandatory components of Rosmarinus officinalis. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. When the concentration of cineole in the preparation is more than 25%, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			nominal capacity of the container must not be more than 25 millilitres. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
4298	ROYAL JELLY	A,E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly. The medicine requires the following warning statements on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4299	ROYAL JELLY FRESH	A,E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4300	ROYAL JELLY LYOPHILISED	A,E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4301	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4302	RUBIA CORDIFOLIA	A,H	
4303	RUBIA TINCTORUM	A,H	
4304	RUBUS CHINGII	A,H	
4305	RUBUS CORCHORIFOLIUS	A,H	
4306	RUBUS COREANUS	A,E,H	
4307	RUBUS FRUTICOSUS	A,E,H	
4308	RUBUS IDAEUS	A,E,H	
4309	RUBUS OCCIDENTALIS	A,E,H	
4310	RUBUS PARVIFOLIUS	A,H	
4311	RUBUS ROSIFOLIUS	A,H	
4312	RUDBECKIA HIRTA	A,H	
4313	RUE OIL	A,H	
4314	RUM	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4315	RUMEX ACETOSA	A,H	
4316	RUMEX ACETOSELLA	A,H	
4317	RUMEX CONGLOMERATUS	A,H	
4318	RUMEX CRISPUS	A,E,H	
4319	RUMEX PULCHER	A,H	
4320	RUMEX SCUTATUS	A,H	
4321	RUSCUS ACULEATUS	A,H	
4322	RUTA GRAVEOLENS	A,E,H	
4323	RUTOSIDE	A,E	
4324	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4325	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4326	S-ISOPROPYL 3-METHYLTHIOCROTONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4327	SABINENE HYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4328	SACCHARIN	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect).
4329	SACCHARIN SODIUM	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect). When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4330	SACCHAROMYCES CEREVISIAE	A,E	When for topical use, the concentration in the medicine must be no more than 1%.
4331	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	When for topical use, the concentration in the medicine must be no more than 1%.
4332	SACCHAROMYCES CERVISIAE POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4333	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4334	SACCHARUM OFFICINARUM	A,E,H	
4335	SAFFLOWER OIL	A,E,H	
4336	SAFFRON	E	Permitted for use as a colour for oral and topical use.
4337	SAGE LEAF DRY	A,E,H	Thujone is a mandatory component of Sage leaf dry. The concentration of thujone in the medicine must be no more than 4%.
4338	SAGE LEAF POWDER	A,H	Thujone is a mandatory component of Sage leaf powder. The concentration of thujone in the medicine must be no more than 4%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4339	SAGE OIL DALMATIAN	A	Thujone is a mandatory component of Sage oil dalmation. The concentration of thujone in the medicine must be no more than 4%. When the concentration of Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
4340	SAGE OIL SPANISH	A,E,H	
4341	SALICORNIA EUROPAEA EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4342	SALICYLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4343	SALICYLIC ACID	E,H	Only for use in topical medicines for dermal application.
4344	SALIX ALBA	A,E,H	
4345	SALIX DAPHNOIDES	A,H	
4346	SALIX DISCOLOR	A,H	
4347	SALIX FRAGILIS	A,H	
4348	SALIX NIGRA	A,H	
4349	SALIX PURPUREA	A,H	
4350	SALSOLA KALI	A,H	
4351	SALVIA CHINENSIS	A,H	
4352	SALVIA FRUTICOSA	A,H	
4353	SALVIA HISPANICA	A,E,H	
4354	SALVIA LAVANDULAEFOLIA	A,H	
4355	SALVIA MILTIORRHIZA	A,H	
4356	SALVIA OFFICINALIS	A,E,H	Thujone is a mandatory component of Salvia officinalis. The concentration of thujone in the medicine must be no more than 4%.
4357	SALVIA SCLAREA	A,E,H	
4358	SAMBUCUS CANADENSIS	A,H	
4359	SAMBUCUS EBULUS	A,H	
4360	SAMBUCUS NIGRA	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4361	SANDALWOOD OIL EAST INDIAN	A,E,H	
4362	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4363	SANICULA EUROPAEA	A,H	
4364	SANTALUM ALBUM	A,E,H	
4365	SANTALUM SPICATUM	A,E,H	The route of administration must be topical or inhalation. The plant preparation must be oil. The plant part must be root or stem wood including heartwood.
4366	SAPINDUS MUKOROSSI	A,H	
4367	SAPONARIA OFFICINALIS	A,H	
4368	SAPOSHNIKOVIA DIVARICATA	A,H	
4369	SARCOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4370	SARGASSUM FUSIFORME	A,H	Iodine is a mandatory component of Sargassum fusiforme. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4371	SARGASSUM SILIQUASTRUM	A,H	Iodine is a mandatory component of Sargassum siliquastrum. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4372	SASSAFRAS ALBIDUM	A,H	Safrole is a mandatory component of Sassafras albidum. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
4373	SATUREIA HORTENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4374	SATUREIA MONTANA	A,H	
4375	SAUROPUS SPATULIFOLIUS	A,H	
4376	SAURURUS CHINENSIS	A,H	
4377	SAUSSUREA COSTUS	A,H	
4378	SAVORY OIL SUMMER	A,H	
4379	SAXIFRAGA GRANULATA	A,E,H	
4380	SCAPHIUM SCAPHIGERUM	A,H	
4381	SCHEFFLERA HEPTAPHYLLA	A,H	
4382	SCHINOPSIS QUEBRACHO-COLORADO	A,H	
4383	SCHINUS MOLLE	A,H	
4384	SCHINUS MOLLE OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4385	SCHISANDRA CHINENSIS	A,E,H	
4386	SCHIZONEPETA TENUIFOLIA	A,E,H	
4387	SCHOENOCAULON OFFICINALE	A,H	The maximum recommended daily dose must contain no more than the equivalent of 1mg of the dry herbal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			material.
4388	SCLAREOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4389	SCLAREOLIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4390	SCLERANTHUS ANNUUS	A,H	
4391	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4392	SCOPOLIA CARNIOLICA	A,H	The concentration of equivalent dry Scopolia carniolica in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4393	SCROPHULARIA NINGPOENSIS	A,H	
4394	SCROPHULARIA NODOSA	A,H	
4395	SCURRULA PARASITICA VAR. GRACILIFLORA	A,H	
4396	SCUTELLARIA BAICALENSIS	A,E,H	
4397	SCUTELLARIA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	BARBATA		
4398	SCUTELLARIA LATERIFLORA	A,E,H	
4399	SEA WHIP EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4400	SEC-BUTYL THIOISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4401	SEC BUTYL 3-METHYLBUT-2-ENETHIOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4402	SECALE CEREALE	A,H	Gluten is a mandatory component of Secale cereale when the plant part is seed and the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			effect).
4403	SEDUM ACRE	A,H	
4404	SELAGINELLA TAMARISCINA	A,H	
4405	SELENICEREUS GRANDIFLORUS	A,E,H	
4406	SELENIUM	H	Only for use as an active homoeopathic ingredient. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'
4407	SELENOCYSTEINE	A	Selenium is a mandatory component of Selenocysteine for oral and sublingual use. The percentage of selenium from Selenocysteine should be calculated based on the molecular weight of Selenocysteine. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4408	SELENOMETHIONINE	A	Selenium is a mandatory component of Selenomethionine for oral and sublingual use. The percentage of selenium from Selenomethionine should be calculated based on the molecular weight of Selenomethionine. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded. 'The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4409	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4410	SEMECARPUS ANACARDIUM	A,H	When the plant part is other than seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
4411	SEMOLINA	E	
4412	SEMPERVIVUM TECTORUM	A,H	
4413	SENEGA ROOT DRY	A,H	
4414	SENEGA ROOT POWDER	A,H	
4415	SENNA ALEXANDRINA	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect)

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			your healthcare practitioner' (or words to that effect).
4416	SENNA FRUIT ALEXANDRIAN DRY	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Fruit Alexandrian Dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) ‘If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) ‘Drink plenty of water' (or words to that effect)

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4417	SENNA FRUIT ALEXANDRIAN POWDER	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Fruit Alexandrian Powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4418	SENNA FRUIT TINNEVELLY DRY	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Fruit Tinnevelly Dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4419	SENNA FRUIT TINNEVELLY POWDER	A,H	When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Fruit Tinnevelly Powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4420	SENNA LEAF DRY	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calculated as sennoside B is a mandatory component of Senna Leaf Dry. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children under 12 years is not recommended’ - (LAX2) ‘Prolonged use may cause serious bowel problems’ - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) ‘If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) ‘Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4421	SENNA LEAF POWDER	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Leaf Powder. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems' - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4422	SENNA TORA	A,H	When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX2) 'Prolonged use may cause serious bowel problems' - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			this product' (or words to that effect) - (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect) When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]' - (LAX4) 'This product may have laxative effect' When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended' - (LAX1) 'Drink plenty of water' (or words to that effect) - (LAX2) 'Prolonged use may cause serious bowel problems'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (S) 'If symptoms persist consult your healthcare practitioner' (or words to that effect).
4423	SEPIA	H	Only for use as an active homoeopathic ingredient.
4424	SEQUOIA SEMPERVIRENS	A,H	
4425	SEQUOIADENDRON GIGANTEUM	A,H	
4426	SERENOA REPENS	A,H	
4427	SERINE	A,E	
4428	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4429	SESAME OIL	A,E,H	
4430	SESAME SEED	E	
4431	SESAMUM INDICUM	A,E,H	
4432	SETARIA ITALICA	A,H	
4433	SHARK-LIVER OIL	A,E	Vitamin A and Colecalciferol are mandatory components of Shark-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life' is permitted only for oral use. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate.’ or ‘Vitamin supplements should not replace a balanced diet.’
4434	SHARK CALCIUM CHONDROITIN SULFATE	A	
4435	SHARK CARTILAGE	A,E	The medicine requires the following warning statement on the medicine label: - (SHARK) 'Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice' (or words to that effect)
4436	SHARK CHONDROITIN SULFATE	A	
4437	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4438	SHARK SODIUM CHONDROITIN	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	SULFATE		
4439	SHEA BUTTER	E	
4440	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4441	SHELLAC	E	
4442	SHEPHERD'S PURSE HERB DRY	A,H	
4443	SHEPHERD'S PURSE HERB POWDER	A,H	
4444	SHERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4445	SIGESBECKIA ORIENTALIS	A,E,H	
4446	SILICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4447	SILICA DIMETHYL SILYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4448	SILICA SILYLATE	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
4449	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4450	SILICON DIOXIDE	A,E,H	Only for use when the route of administration is other than inhalation. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4451	SILICONE QUATERNIUM-8	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect).
4452	SILVER	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 1%.
4453	SILVER BEET	E,H	
4454	SILVER BOROSILICATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			should be no more than 0.6%. Silver is a mandatory component of Silver borosilicate when the route of administration is topical. The concentration of silver in the medicine must be no more than 1%.
4455	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4456	SILYBUM MARIANUM	A,E,H	
4457	SIMABA CEDRON	A,H	
4458	SIMETHICONE	E	
4459	SIMMONDSIA CHINENSIS	A,E,H	
4460	SINAPIS ALBA	A,H	Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed. When the herbal substance is derived from the seed then the maximum recommended daily dose must not provide more than 20 mg of allyl isothiocyanate.
4461	SINAPIS ARVENSIS	A,H	
4462	SINOMENIUM ACUTUM	A,H	
4463	SIPHONESTEGIA CHINENSIS	A,H	
4464	SIRAITIA GROSVENORII	A,E,H	
4465	SISYMBRIUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	OFFICINALE		
4466	SKATOLE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4467	SKIPJACK-LIVER OIL	A,E	Vitamin A and Colecalciferol are mandatory components of Skipjack-liver oil. When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. Divided preparations for internal use must contain more than 33 micrograms of Retinol Equivalents per dosage unit and no more than 3000 micrograms of Retinol Equivalents of Vitamin A in the maximum daily dose. Undivided preparations for internal use must contain more than 33 micrograms Retinol Equivalents per gram of vitamin A and no more than 3000 micrograms of Retinol

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Equivalents of Vitamin A in the maximum daily dose. When for use in adults the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' The indication 'Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life' is permitted only for oral use. When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4468	SLIPPERY ELM BARK DRY	A,H	
4469	SLIPPERY ELM BARK POWDER	A,E,H	
4470	SMILAX ARISTOLOCHIIFOLIA	A,H	
4471	SMILAX CHINA	A,H	
4472	SMILAX GLABRA	A,H	
4473	SMILAX OFFICINALIS	A,E,H	
4474	SMILAX ORNATA	A,E,H	
4475	SMOKE EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4476	SODIUM ACETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4477	SODIUM ACETYLATED	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HYALURONATE		dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4478	SODIUM ACID CITRATE	A,E,H	When used as an active ingredient, only for use in oral medicines. When used as an active, only for use in oral medicines. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4479	SODIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.8%.
4480	SODIUM ACRYLATES CROSSPOLYMER-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.7 % (w/w).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4481	SODIUM ACRYLOYDIMETHYLTAURATE/VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% (w/w).
4482	SODIUM ALGINATE	E	
4483	SODIUM ASCORBATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, the equivalent quantity of sodium is required in the application and also on the product label. The percentage of sodium from sodium ascorbate should be calculated based on the molecular weight of sodium ascorbate. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).' When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4484	SODIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When used in a sunscreen, the concentration in the medicine must be no more than 0.1%. When used in products other than sunscreens, the concentration in the medicine must be no more than 0.5%.
4485	SODIUM ASCORBYL/CHOLESTERYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4486	SODIUM BENZOATE	E	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4487	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A,H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4488	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A,H	
4489	SODIUM BICARBONATE	A,E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). When used as an active ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Medicines for use as oral rehydration therapy are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001. The medicine requires the following warning statements on the medicine label: - (UOAD) 'Use only as directed' - (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice' (or words to that effect) - (DIAR3) 'If diarrhoea persists, seek medical advice.' - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			before use. Keep out of reach of children'.
4490	SODIUM BISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4491	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4492	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4493	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4494	SODIUM CARBONATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4495	SODIUM CARBONATE MONOHYDRATE	E,H	Only for use as an active homoeopathic or excipient ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4496	SODIUM CARBOXYMETHYL BETAGLUCAN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
4497	SODIUM CARRAGEENAN	E	
4498	SODIUM CASEINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4499	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4500	SODIUM CHLORIDE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, sodium is a mandatory component of Sodium chloride. The percentage of sodium from Sodium chloride should be calculated on the molecular weight of Sodium chloride. If used as an active ingredient and the medicine is intended as a mineral supplementation, the equivalent quantity of sodium is required in the application and also on the product label. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			only permitted when the medicine is for oral or sublingual use. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4501	SODIUM CHONDROITIN SULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.001%.
4502	SODIUM CITRATE	A,E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4503	SODIUM CITRATE DIHYDRATE	A,E	Only for oral use when used as an active ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4504	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
4505	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4506	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4507	SODIUM CYCLAMATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4508	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application. Medicines containing the antimicrobial preservative sodium dehydroacetate require the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (SDACET) 'Contains sodium dehydroacetate' (or words to that effect).
4509	SODIUM DNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4510	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4511	SODIUM ERYTHORBATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4512	SODIUM ETHYL HYDROXYBENZOATE	E	
4513	SODIUM FLUORIDE	A,E,H	Fluoride is a mandatory component of Sodium fluoride. The percentage of fluoride from sodium fluoride should be calculated based on the molecular weight of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			sodium fluoride. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. c) When the concentration of fluoride ion is more than 1,000 mg/kg, any claims made regarding the medicine in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay. In products, other than dental products, the concentration of fluoride in the product from all ingredients must not exceed 15 mg/kg or 15 mg/L or 0.0015%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(or words to that effect).
4514	SODIUM FUMARATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4515	SODIUM GLYCEROPHOSPHATE	A,E,H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4516	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4517	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4518	SODIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4519	SODIUM HYDROXYCITRATE	A	The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4520	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4521	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4522	SODIUM HYPOCHLORITE	E,H	Only for use as an active homoeopathic or excipient ingredient. Chlorine is a mandatory component

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of Sodium hypochlorite. The concentration of chlorine in the medicine must be no more than 4%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4523	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4524	SODIUM LACTATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4525	SODIUM LAURETH SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4526	SODIUM LAUROAMPHOACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4527	SODIUM LAUROYL METHYL ISETHIONATE	E	Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 11%.
4528	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4529	SODIUM LAURYL PHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4530	SODIUM LAURYL SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4531	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4532	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4533	SODIUM MANNOSE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4534	SODIUM METABISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4535	SODIUM METHYL COCOYL TAURATE	E	Only for dental use. The concentration in the medicine must be no more than 2%.
4536	SODIUM METHYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4537	SODIUM MOLYBDATE DIHYDRATE	A	Only for use in oral medicines. Molybdenum is a mandatory component of Sodium molybdate dihydrate. The percentage of molybdenum from

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate. The maximum daily dose of molybdenum from sodium molybdate dihydrate must be no more than 125 micrograms.
4538	SODIUM MONOFLUOROPHOSPHATE	A	Fluoride is a mandatory component of sodium monofluorophosphate. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active ingredient, it is subject to the following conditions: a) Only for use in combination with at least one other listable therapeutically active ingredient. b) The concentration of fluoride ion must be no more than 1,500 mg/kg. c) When the concentration of fluoride ion is more than 1,000 mg/kg, any claims made regarding the medicine in relation to fluoride content are restricted to those relating to improvements in dental hygiene or the use of fluoride for the prevention of tooth decay. In products, other than dental products, the concentration of fluoride in the product from all ingredients must not exceed 15 mg/kg or 15 mg/L or 0.0015%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4539	SODIUM MYRISTOYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0164%.
4540	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4541	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4542	SODIUM PANTOTHENATE	A,E,H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4543	SODIUM PCA	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4544	SODIUM PERBORATE	A,H	Boron is a mandatory component of sodium perborate. The percentage of boron from sodium perborate should be calculated based on the molecular weight of sodium perborate. When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron. When used preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4545	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4546	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4547	SODIUM POLYMETAPHOSPHATE	E	
4548	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application. Medicines for topical use containing the antimicrobial preservative sodium propionate requires the following warning statement on the medicine label: - (SPROP) 'Contains sodium propionate' (or words to that effect).
4549	SODIUM PROPYL HYDROXYBENZOATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			to this effect) if product contains one hydroxybenzoate source.
4550	SODIUM RNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
4551	SODIUM SELENATE	A,H	Selenium is a mandatory component of sodium selenite. The percentage of selenium from Sodium selenite should be calculated based on the molecular weight of Sodium selenite. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4552	SODIUM SELENITE	A,H	Selenium is a mandatory component of Sodium selenite. The percentage of selenium from Sodium selenite should be calculated

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			based on the molecular weight of Sodium selenite. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4553	SODIUM SELENITE PENTAHYDRATE	A,H	Selenium is a mandatory component of Sodium selenite pentahydrate. The percentage of selenium from sodium selenite pentahydrate should be calculated based on the molecular weight of sodium selenite pentahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 mcg for adults of selenium from dietary

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			supplements should not be exceeded.' The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4554	SODIUM SILICATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4555	SODIUM STARCH GLYCOLLATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4556	SODIUM STARCH	E	When for oral or sublingual use and the total amount of sodium from all

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	GLYCOLLATE TYPE A		ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4557	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4558	SODIUM STEAROXY PG-HYDROXYETHYLCELL ULOSE SULFONATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4559	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4560	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4561	SODIUM STEARYL PHTHALAMATE	E	Only for use in medicines medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4562	SODIUM SUCCINATE	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
4563	SODIUM SULFATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of sodium sulfate. When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).
4564	SODIUM SULFATE DECAHYDRATE	A,E,H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of sodium sulfate decahydrate. When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label: - (LAX4) 'Substance may have a laxative effect'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4565	SODIUM SULFITE	E,H	Only for use as an active homoeopathic ingredient. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4566	SODIUM SULFITE	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	HEPTAHYDRATE		dermal application. Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4567	SODIUM TRIPOLYPHOSPHATE	E	Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4568	SOLANUM DULCAMARA	A,H	When for internal use, steroidal alkaloids calculated as solamine is a mandatory component of Solanum dulcamara. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4569	SOLANUM FEROX	A,H	When for internal use, steroidal alkaloids calculated as solamine is a mandatory component of Solanum ferox. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			alkaloids calculated as solanine.
4570	SOLANUM LYCOCARPUM FRUIT EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4571	SOLANUM MELONGENA	A,H	When for internal use, steroidal alkaloids calculated as solamine is a mandatory component of Solanum melongena. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4572	SOLANUM NIGRUM	A,H	When for internal use, steroidal alkaloids calculated as solamine is a mandatory component of Solanum nigrum. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4573	SOLANUM TUBEROSUM	A,H	When for internal use, steroidal alkaloids calculated as solamine is a mandatory component of Solanum tuberosum. When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4574	SOLIDAGO GIGANTEA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4575	SOLIDAGO GIGANTEA MIS	A,E,H	
4576	SOLIDAGO VIRGAUREA	A,E,H	
4577	SOLUBLE MAIZE STARCH	E	
4578	SOLUBLE POTATO STARCH	E	
4579	SOLVENT GREEN 3	E	Permitted for use as a colour for topical use.
4580	SOLVENT RED 1	E	Permitted for use as a colour for topical use.
4581	SOLVENT VIOLET 13	E	Permitted for use as a colour for topical use.
4582	SOLVENT YELLOW 172	E	Permitted for use as a colour for topical use. The concentration in the medicine must be no more than 0.3%.
4583	SOLVENT YELLOW 33	E	Permitted for use as a colour for topical use.
4584	SOPHORA FLAVESCENS	A,E,H	
4585	SOPHORA TONKINENSIS	A,H	
4586	SORBIC ACID	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4587	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4588	SORBITAN MONO-OLEATE	E	
4589	SORBITAN MONOLAURATE	E	
4590	SORBITAN MONOSTEARATE	E	
4591	SORBITAN OLEATE	E	
4592	SORBITAN OLIVATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4593	SORBITAN PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4594	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4595	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4596	SORBITAN STEARATE	E	
4597	SORBITAN	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	TRISTEARATE		dermal application.
4598	SORBITOL	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) ‘Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).
4599	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A,E	Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (crystallising). When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
4600	SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING)	A,E	Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (non-crystallising).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
4601	SORBUS AUCUPARIA	A,H	
4602	SORBUS DOMESTICA	A,H	
4603	SORGHUM	E	
4604	SORGHUM VULGARE	A,H	
4605	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	Soy phosphatidylserine is a mandatory component of Soy Phosphatidylserine-Enriched Soy Lecithin Liquid. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4606	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of Soy Phosphatidylserine-Enriched Soy Lecithin Powder. The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4607	SOY POLYSACCHARIDE	E	
4608	SOY PROTEIN	E	
4609	SOY STEROL	E	
4610	SOYA BEAN	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4611	SOYA BRAN	E	
4612	SOYA OIL	A,E,H	
4613	SOYBEAN FLOUR	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4614	SOYBEAN GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4615	SPARGANIUM STOLONIFERUM	A,H	
4616	SPARTIUM JUNCEUM	A,H	
4617	SPATHOLOBUS SUBERECTUS	A,H	
4618	SPEARMINT OIL	A,E,H	
4619	SPEARMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4620	SPHINGOLIPIDS	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4621	SPIGELIA ANTHELMIA	A,H	
4622	SPIGELIA MARILANDICA	A,H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4623	SPIKE LAVENDER OIL	A,E,H	Camphor is a mandatory component of spike lavender oil. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
4624	SPINACH	E	
4625	SPINACIA OLERACEA	A,E,H	
4626	SPIRODELA POLYRRHIZA	A,H	
4627	SPIRULINA	E	
4628	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
4629	SPRAY-DRIED LIQUID GLUCOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4630	SPRUCE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4631	SQUALANE	E	Only for use in topical medicines for dermal application.
4632	SQUALENE	A,E	
4633	SQUID OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use.
4634	SQUILL DRY	A,H	
4635	SQUILL INDIAN DRY	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4636	SQUILL INDIAN POWDER	A,H	
4637	SQUILL POWDER	A,H	
4638	ST JOHN'S WORT DRY EXTRACT QUANTIFIED	A	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4639	ST JOHN'S WORT HERB DRY	A,H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4640	ST JOHN'S WORT HERB POWDER	A,H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4641	STACHYS OFFICINALIS	A,E,H	
4642	STACHYS PALUSTRIS	A,H	
4643	STACHYURUS HIMALAICUS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4644	STANNIC OXIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
4645	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4646	STAR ANISE OIL	A,E	When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4647	STARCH	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4648	STARCH SODIUM OCTENYL SUCCINATE	E	
4649	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4650	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4651	STEARAMIDE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4652	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4653	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4654	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 2%. When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4655	STEARETH-10	E	Only for use in topical medicines for dermal application.
4656	STEARETH-100	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4657	STEARETH-2	E	Only for use in topical medicines for dermal application.
4658	STEARETH-20	E	Only for use in topical medicines for dermal application.
4659	STEARETH-21	E	Only for use in topical medicines for dermal application.
4660	STEARETH-5	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4661	STEARIC ACID	E	
4662	STEAROPTENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4663	STEAROXY DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4664	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4665	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4666	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4667	STEARYL ALCOHOL	E	
4668	STEARYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.5%. The medicine requires the following warning statements on the medicine label: - (EYE2) 'May be irritant to the eyes'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			(or words to that effect) - (EYE) 'Avoid contact with eyes' (or words to that effect).
4669	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4670	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4671	STEARYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4672	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4673	STELLARIA CHAMAEJASME	A,H	
4674	STELLARIA DICHOTOMA	A,H	
4675	STELLARIA MEDIA	A,E,H	
4676	STEMONA JAPONICA	A,H	
4677	STEMONA SESSILIFOLIA	A,H	
4678	STENOTAPHRUM SECUNDATUM	A,H	
4679	STEPHANIA TETRANDA	A,H	
4680	STERCULIA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4681	STERCULIA TRAGACANTHA	A,H	
4682	STERCULIA URENS	A,H	
4683	STEVIA REBAUDIANA	A,E,H	
4684	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4685	STILLINGIA SYLVATICA	A,H	
4686	STORAX PREPARED	A,E,H	
4687	STRAWBERRY	E	
4688	STRAWBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4689	STREPTOCOCCUS THERMOPHILUS	A	
4690	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of dilute ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4691	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4692	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4693	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4694	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4695	STRYCHNOS NUX-VOMICA	A,H	Strychnine (of Strychnos spp.) is a mandatory component of Strychnos nux-vomica. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4696	STYPHNOLOBIUM JAPONICUM	A,E,H	
4697	STYRAX BENZOIN	A,E,H	
4698	STYRAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4699	STYRAX PARALLELONEURUM	A,H	
4700	STYRAX TONKINENSIS	A,H	
4701	STYRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4702	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4703	STYROLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4704	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4705	SUCCINIC ACID	E	
4706	SUCRALOSE	E	
4707	SUCROSE	E,H	Only for use as an active homoeopathic ingredient. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
4708	SUCROSE ACETATE ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4709	SUCROSE COCOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4710	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4711	SUCROSE LAURATE	E	When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4712	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4713	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4714	SUCROSE POLYCOTTONSEEDATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4715	SUCROSE STEARATE	E	For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.25%. For oral use as a manufacturing aid only. When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4716	SUDAN III	E	Permitted for use as a colour for topical use.
4717	SUGAR CANE WAX ALCOHOLS	A,H	The maximum recommended daily dose must not provide more than 12mg. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
4718	SUGARCANE	E,H	When for oral or sublingual use, sucrose is a mandatory component of Sugarcane. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			words to that effect).
4719	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4720	SULFATED LOW MOLECULAR WEIGHT FUCANS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025%.
4721	SULFUR DIOXIDE	E	Medicines containing sulfites salts require the following warning statement on the medicine label: - (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.
4722	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4723	SULFURIC ACID	E,H	Only for use as an active homoeopathic ingredient or excipient ingredient. The concentration in the medicine must be no more than 0.5%.
4724	SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4725	SULISOBENZONE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4726	SULISOBENZONE SODIUM	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
4727	SUNFLOWER OIL	A,E,H	
4728	SUNFLOWER SEED	E,H	
4729	SUNSET YELLOW FCF	E	Permitted for use as a colour for oral and topical use.
4730	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use.
4731	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4732	SWEDE	E	
4733	SWEET ORANGE OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
4734	SWEET POTATO	E	
4735	SWERTIA CHIRATA	A,H	
4736	SWIETENIA MAHOGANI	A,H	
4737	SYAGRUS ROMANZOFFIANA	A,E,H	
4738	SYMPHYTUM OFFICINALE	H	When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more. When used in topical medicines for dermal application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
4739	SYMPLOCARPUS FOETIDUS	A,H	
4740	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4741	SYNTHETIC TERPENE RESIN	E	Only for use in topical, oral or oral application medicines. When the route of administration is oral, the dosage form must be chewing gum.
4742	SYNTHETIC WAX	E	
4743	SYRINGA RETICULATA	A,H	
4744	SYRINGA VULGARIS	A,H	
4745	SYZYGIUM	A,E,H	When the plant preparation is oil or distillate and the concentration of this

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	AROMATICUM		oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the plant preparation is oil or distillate, the concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.
4746	SYZYGIUM CUMINI	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4747	TABEBUIA SERRATIFOLIA	A,E,H	
4748	TAGETES ERECTA	A,H	
4749	TAGETES MINUTA	A,E,H	
4750	TAGETES OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4751	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4752	TALLOW	E	Only for use in topical medicines for dermal application.
4753	TALLOW GLYCERIDES	E	
4754	TAMARINDUS INDICA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4755	TAMARIX APHYLLA	A,H	
4756	TAMARIX CHINENSIS	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4757	TAMARIX GALLICA	A,H	
4758	TAMUS COMMUNIS	A,H	If the plant part is fruit or root, the maximum recommended daily dose must be no more than 1mg of the equivalent dry fruit or dry root of Tamus communis.
4759	TANACETUM CINERARIIFOLIUM	A,H	The concentration in the medicine must be no more than 10%.
4760	TANACETUM PARTHENIUM	A,E,H	
4761	TANACETUM VULGARE	A,H	Oil (of Tanacetum vulgare) is a mandatory component of Tanacetum vulgare. The concentration of oil (of Tanacetum vulgare) in the medicine must be no more than 0.8%.
4762	TANGERINE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4763	TANGERINE OIL COLDPRESSED	A,E,H	When used internally, oxedrine is a mandatory component of tangerine oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
4764	TANNIC ACID	E,H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			homoeopathic ingredient or excipient ingredient.
4765	TAPIOCA STARCH	E	
4766	TARAXACUM MONGOLICUM	A,E,H	
4767	TARAXACUM OFFICINALE	A,E,H	
4768	TARO	E	
4769	TARRAGON OIL	A,E,H	
4770	TARTARIC ACID	E,H	Only for use as an active homoeopathic ingredient.
4771	TARTRAZINE	E	Permitted for use as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4772	TARTRAZINE ALUMINIUM LAKE	E	Permitted for use as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4773	TASMANNIA LANCEOLATA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
4774	TAURINE	A,E	
4775	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4776	TERMINALIA ARJUNA	A	Only for use in oral medicines. Only for use when the plant part is bark. The maximum recommended daily dose must be no more than 6 grams of Terminalia arjuna dried bark or its extract equivalents. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (CHILD2) 'Not suitable for children'.
4777	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4778	TERMINALIA CATAPPA	A,H	
4779	TERMINALIA CHEBULA	A,H	
4780	TERMINALIA FERDINANDIANA	A,E,H	Only for use when the plant part is fruit flesh, fruit flesh dry or the preparation is as an aqueous extract of the fruit flesh. When used as an excipient, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than 0.3%.
4781	TERMINALIA SERICEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. Only for use when the plant part is root bark. Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is approved. The concentration in the medicine must be no more than 0.1%.
4782	TERPINEN-4-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4783	TERPINEOL	E	
4784	TERPINEOL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4785	TERPINOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4786	TERPINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4787	TERPINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4788	TERPINYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
4789	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4790	TERT-BUTYL HYDROQUINONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4791	TERT-BUTYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4792	TERT-BUTYLPYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4793	TETRACLINIS ARTICULATA	A,E,H	
4794	TETRADECYL AMINOBUTYROYLVALYLAMINOBUTYRIC UREA TRIFLUOROACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4795	TETRADIUM RUTICARPUM	A,H	When for internal use, oxedrine is a mandatory component of Tetradium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			ruticarpum. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4796	TETRAHEXYLDECYL ASCORBATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4797	TETRAHYDRO-6-(3-PENTENYL)-2H-PYRAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4798	TETRAHYDRO LINALYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4799	TETRAHYDRO PARA-METHYLQUINOLINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4800	TETRAHYDRODIFERULOYLMETHANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.1%.
4801	TETRAHYDROFURFURYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4802	TETRAHYDROGERANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4803	TETRAHYDROLINALOOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4804	TETRAHYDROMUGUOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4805	TETRAHYDROMYRCENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4806	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4807	TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4808	TETRAPANAX PAPYRIFER	A,H	
4809	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4810	TETRASODIUM PYROPHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4811	TEUCRIUM CHAMAEDRYS	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Teucrium chamaedrys.
4812	TEUCRIUM MARUM	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4813	TEUCRIUM SCORODONIA	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4814	THAPSIA GARGANICA	A,H	
4815	THAUMATIN	E	
4816	THEASPIRANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4817	THEMEDA TRIANDRA	A,H	
4818	THEOBROMA CACAO	A,E,H	Caffeine is a mandatory component of Theobroma cacao. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
4819	THEOBROMA OIL	A,E,H	
4820	THEOBROMA PREPARED	A,E,H	Caffeine is a mandatory component of Theobroma Prepared. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			quantity per dosage unit or per mL or per gram of product]'.
4821	THIAMINE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4822	THIAMINE HYDROCHLORIDE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4823	THIAMINE NITRATE	A,E	When used as an active ingredient and the route of administration is oral or sublingual, the medicine requires the following warning statement on the medicine label: - (VIT) 'Vitamins can only be of assistance if the dietary vitamin intake is inadequate.' or 'Vitamin supplements should not replace a balanced diet.'
4824	THIOCINEOLE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4825	THIOTAURINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4826	THLASPI ARVENSE	A,E,H	
4827	THREONINE	A,E	
4828	THUJA OCCIDENTALIS	A,H	
4829	THUJA PLICATA	A,E,H	
4830	THYME HERB DRY	A,E,H	
4831	THYME OIL	A,E,H	When the concentration of Thyme oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the warning statement: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4832	THYMOL	A,E	When used as an active ingredient, the product code must be medicated space spray and medicated throat lozenges. When used as an excipient, only for use in topical medicines for dermal applications. When used topically the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			requires the following warning statement on the medicine label: - (THYMOL) 'Contains thymol [quantity]' (or words to that effect).
4833	THYMUS CAPITATUS	A,E,H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more that 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4834	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4835	THYMUS MASTICHINA	A,E,H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more that 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4836	THYMUS SERPYLLUM	A,E,H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			of reach of children' (or words to that effect).
4837	THYMUS VULGARIS	A,E,H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4838	THYMUS VULGARIS MIS	A,E,H	When the plant preparation is an oil or a distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris mis oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4839	THYMUS ZYGIS	A,H	When the plant preparation is an oil or a distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus zygis oil or distillate in the preparation is greater than 50%, a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4840	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4841	TILACTASE	A	Must be derived from Aspergillus oryzae and comply with the relevant USP monograph. When the dosage form is undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted. When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.
4842	TILIA CORDATA	A,E,H	
4843	TILIA PLATYPHYLLOS	A,E,H	
4844	TILIA TOMENTOSA	A,H	
4845	TILIA X VULGARIS	A,E,H	
4846	TILIANTOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4847	TIN	H	Only for use as an active homoeopathic ingredient.
4848	TINOSPORA SINENSIS	A,H	
4849	TITANIUM DIOXIDE	A,E	Only for use as an active ingredient in sunscreens. Permitted for use as a colour for oral and topical use. Only for use in topical medicines as a colour for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 25%.
4850	TOCOCYSTEAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
4851	TOCOFERSOLAN	E	Only for oral and topical use. When for oral use, the concentration in the medicine must be no more than 10% w/w. When used in topical medicines for dermal application, it is not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.1%
4852	TOCOPHEROL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4853	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4854	TOCOPHERYL NICOTINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must not exceed 0.3%.
4855	TOLU BALSAM	A,E,H	
4856	TOLUENE	E	The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.089%.
4857	TOLYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4858	TOLYLALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	GLYCERYLACETAL		flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4859	TOMATO	E,H	Only for use as an active homoeopathic ingredient.
4860	TONKA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4861	TONKA BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4862	TONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4863	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4864	TOXICODENDRON PUBESCENS	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron pubescens.
4865	TOXICODENDRON RADICANS	A,H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4866	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4867	TRACHELOSPERMUM JASMINOIDES	A,E,H	
4868	TRACHYSPERMUM AMMI	A,E	Only for use in oral medicines when the plant part is fruit or seed. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect) - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4869	TRAGACANTH	A,E	
4870	TRAMETES VERSICOLOR	A,H	Trametes versicolor hyphae dry extract must only be prepared using water.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4871	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A,H	Only for use in oral medicines.
4872	TRANS-1-(2,4,4-TRIMETHYL-2-CYCLOHEXEN-1-YL)-2-BUTEN-1-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4873	TRANS-2-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4874	TRANS-2-DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4875	TRANS-2-HEPTEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4876	TRANS-2-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4877	TRANS-2-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4878	TRANS-2-HEXENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4879	TRANS-2-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4880	TRANS-2-HEXENYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			concentration in a medicine must be no more than 5%.
4881	TRANS-2-HYDROXYCINNAMIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4882	TRANS-2-UNDECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4883	TRANS-3-HEXENOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4884	TRANS-4-DECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4885	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4886	TRANS-ETHYL 2-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4887	TRANS-METHYL-2-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4888	TRANS,TRANS-2,4-DECADIEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4889	TRANS,TRANS-2,4-HEXADIENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. The maximum daily dose must provide no more than 13.5 mg of Trans,Trans-2,4-Hexadienal.
4890	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Treacle. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
4891	TREFRIW WELLS MINERAL WATER	A	When for internal use, iron is a mandatory component of Trefriw Wells mineral water. Solid dosage forms containing more than 5 milligrams of elemental iron in each dosage unit are required to have a child resistant closure. Liquid Preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure. Only able to be used when presented

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			in single use sachets for therapeutic use as an iron supplement. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4892	TREHALOSE DIHYDRATE	E	Only for use in topical medicines for dermal application.
4893	TREMELLA FUCIFORMIS	A,H	
4894	TRIACETIN	E	
4895	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4896	TRIADICA SEBIFERA	A,H	
4897	TRIBASIC POTASSIUM PHOSPHATE	A,E,H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of tribasic potassium phosphate. The percentage of potassium from tribasic potassium phosphate should be calculated based on the molecular weight of tribasic potassium phosphate. When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
4898	TRIBASIC SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4899	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4900	TRIBEHENIN PEG-20 ESTERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4901	TRIBULUS TERRESTRIS	A,E,H	
4902	TRIBUTYL ACETYLCITRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4903	TRICALCIUM PHOSPHATE	E	
4904	TRICAPRYLIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4905	TRICAPRYLYL CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
4906	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4907	TRICHLOROMETHYLPHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4908	TRICHODERMA VIRIDE	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4909	TRICHOSANTHES KIRILOWII	A,E,H	
4910	TRICLOSAN	E	The concentration in the medicine must be no more than 1%. The medicine requires the following warning statement on the medicine label: - (TRICLO) 'Contains triclosan [quantity]' (or words to that effect).
4911	TRICYCLODECENYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4912	TRIDECANAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4913	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4914	TRIDECETH-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
4915	TRIDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4916	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
4917	TRIDECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 23%.
4918	TRIDECYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4919	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
4920	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
4921	TRIETHOXYCAPRYLYLSILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
4922	TRIETHYL CITRATE	E	
4923	TRIETHYLENE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	GLYCOL		
4924	TRIFOLIUM PRATENSE	A,E,H	
4925	TRIFOLIUM REPENS	A,H	
4926	TRIGONELLA FOENUM-GRAECUM	A,E,H	
4927	TRIHYDROXYPALMITAMIDOHYDROXYPROPYL MYRISTYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4928	TRIHYDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
4929	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
4930	TRIISODECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4931	TRIISONONANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4932	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
4933	TRILAURIN	E	Only for use in topical medicines for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			dermal application.
4934	TRILISA ODORATISSIMA	A,H	
4935	TRILLIUM ERECTUM	A,H	
4936	TRIMETHOXYCAPRYL YL SILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.25%.
4937	TRIMETHYL-BICYCLO-HEPTANE-SPIROCYCLOHEXENO NE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4938	TRIMETHYL HYDROXYPENTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4939	TRIMETHYL UNDECYLENIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4940	TRIMETHYLBENZENEP ROPANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
4941	TRIMETHYLHEXANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4942	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
4943	TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4944	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
4945	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
4946	TRIOCTANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4947	TRIOCTYLDODECYL CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 12%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4948	TRIOLEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4949	TRIOSTEUM PERFOLIATUM	A,H	
4950	TRIOXAUNDECANEDIOIC ACID	E	
4951	TRIPAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4952	TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
4953	TRIS-BIPHENYL TRIAZINE	A	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%. When used topically, the dosage form must not be spray.
4954	TRISILOXANE	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 40%.
4955	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
4956	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
4957	TRISODIUM NTA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
4958	TRISTEARIN	E	
4959	TRITICUM AESTIVUM	A,E,H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4960	TRITICUM DURUM	A,E,H	Gluten is a mandatory component

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			when the plant part is seed and the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4961	TRIUNDECANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 11.2%.
4962	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
4963	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
4964	TROLAMINE SALICYLATE	A	Only for use as an active ingredient in sunscreens. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 12%.
4965	TROLLIUS CHINENSIS	A,H	
4966	TROMETAMOL	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4967	TROMETAMOL HYDROCHLORIDE	E	
4968	TROPAEOLUM MAJUS	A,E,H	
4969	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
4970	TROPOLONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
4971	TSUGA CANADENSIS	A,H	
4972	TULIPA EDULIS	A,H	Colchicine is a mandatory component of Tulipa edulis. The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4973	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
4974	TURNERA DIFFUSA	A,E,H	
4975	TURNIP	E	
4976	TURPENTINE OIL	A,E	The concentration in the medicine must be no more than 25%.
4977	TYPHA ANGUSTIFOLIA	A,H	
4978	TYPHA LATIFOLIA	A,H	
4979	TYPHONIUM GIGANTEUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4980	TYROSINE	A,E	

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 2—Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
4981	UBIDECARENONE	A,E	When used as an excipient, the route of administration must be topical. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When used as an excipient, the concentration in a medicine must be no more than 0.05%. The maximum recommended daily dose must provide no more than 300 milligrams of ubidecarenone. When used in combination with Ubiquinol-10, the maximum recommended daily dose must provide no more than 300 milligrams of ubiquinol-10 and ubidecarenone combined. The medicine requires the following warning statement on the medicine label: - (WARF) 'Do not take while on warfarin therapy without medical advice.'
4982	UBIQUINOL-10	A	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			The maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10. When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined. requires the following warning statement on the medicine label: - (WARF) 'Do not take while on warfarin therapy without medical advice.'
4983	ULEX EUROPAEUS	A,H	
4984	ULMUS AMERICANA	A,H	
4985	ULMUS CAMPESTRIS	A,H	
4986	ULMUS GLABRA	A,H	
4987	ULMUS PARVIFOLIA	A,H	
4988	ULMUS PROCERA	A,H	
4989	ULMUS PUMILA	A,H	
4990	ULMUS RUBRA	A,H	
4991	ULTRALIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4992	ULTRAMARINE BLUE	E	Permitted for use as a colour for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			topical use.
4993	ULVA LACTUCA	A,H	Iodine is a mandatory component of Ulva lactuca. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4994	UNCARIA GAMBIR	A,H	
4995	UNCARIA RHYNCOPHYLLA	A,H	
4996	UNCARIA SINENSIS	A,H	
4997	UNCARIA TOMENTOSA	A,H	
4998	UNDARIA PINNATIFIDA	A,H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
4999	UNDECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5000	UNDECANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			no more than 5%.
5001	UNDECENOIC ACID	E	
5002	UNDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5003	UNDECYLCRYLENE DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
5004	UNDECYLENAMIDE DEA	E	
5005	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5006	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5007	UREA	A,E,H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10% (w/w).
5008	URTICA DIOICA	A,E,H	
5009	URTICA URENS	A,H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5010	USNEA BARBATA	A,H	
5011	UVA URSI LEAF DRY	A,H	
5012	UVA URSI LEAF POWDER	A,E,H	
5013	VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	E	Vinyl acetate is a mandatory component of VA/butyl maleate/isobornyl acrylate copolymer. The concentration of vinyl acetate in the medicine must be no more than 0.01% or 100 ppm. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5014	VACCARIA SEGATALIS	A,H	
5015	VACCINIUM BRACTEATUM	A,H	
5016	VACCINIUM CORYMBOSUM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5017	VACCINIUM MACROCARPON	A,E,H	
5018	VACCINIUM MYRTILLOIDES	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5019	VACCINIUM MYRTILLUS	A,E,H	
5020	VACCINIUM OXYCOCCUS	A,H	
5021	VACCINIUM VITIS-IDAEA	A,H	
5022	VALENCENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5023	VALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5024	VALERIAN DRY	A,H	
5025	VALERIAN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5026	VALERIAN POWDER	A,H	
5027	VALERIANA EDULIS	A,H	
5028	VALERIANA OFFICINALIS	A,H	
5029	VALERIANA	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	SORBIFOLIA		
5030	VALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5031	VALINE	A,E	
5032	VANADIUM	H	
5033	VANILLA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5034	VANILLA DRY	A,E,H	
5035	VANILLA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5036	VANILLA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5037	VANILLA PLANIFOLIA	A,E,H	
5038	VANILLA POWDER	A,E,H	
5039	VANILLA TAHITENSIS	A,H	
5040	VANILLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5041	VANILLIN	E	Permitted for use as a flavour.
5042	VANILLIN ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5043	VANILLYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5044	VAT RED 1	E	Permitted for use as a colour for topical use.
5045	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use as a colour for topical use.
5046	VAT RED 5	E	Permitted for use as a colour for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			topical use.
5047	VEGETABLE OIL	E	
5048	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the following warning statements on the medicine label: - (VOPE) 'There is no benefit from taking more than 3g/day of phytosterols from all sources' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
5049	VEIN	H	Only for use as an active homoeopathic ingredient.
5050	VERATRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5051	VERATRUM ALBUM	A,H	Solanidine is a mandatory component of Veratrum album. The concentration of equivalent dry Veratrum album in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
5052	VERBASCUM DENSIFLORUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5053	VERBASCUM THAPSUS	A,H	
5054	VERBENA OFFICINALIS	A,H	
5055	VERBENA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5056	VERONICA CHAMAEDRYS	A,H	
5057	VERONICA OFFICINALIS	A,H	
5058	VERONICASTRUM VIRGINICUM	A,E,H	
5059	VETIVER OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5060	VETIVERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5061	VIBURNUM OPULUS	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5062	VIBURNUM PRUNIFOLIUM	A,E,H	
5063	VICIA FABA	A,H	Levodopa (of Vicia faba) is a mandatory component of Vicia faba. The concentration of Levodopa (of Vicia faba) from all ingredients in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.
5064	VIGNA ANGULARIS VAR. ANGULARIS	A,H	
5065	VIGNA RADIATA	A,H	
5066	VIGNA UMBELLATA	A,H	
5067	VINCA MAJOR	A,H	Vincamine is a mandatory component of Vinca major. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
5068	VINCA MINOR	A,H	Vincamine and vincristine are mandatory components of Vinca minor. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. The concentration of Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%
5069	VINCETOXICUM OFFICINALE	A,H	
5070	VINEGAR	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5071	VIOLA ODORATA	A,E,H	
5072	VIOLA TRICOLOR	A,H	
5073	VIOLA YEDOENSIS	A,H	
5074	VIOLET LEAF ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5075	VIOLET LEAVES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5076	VIPER	H	Only for use as an active homoeopathic ingredient.
5077	VISCUM ALBUM	A,E,H	
5078	VISCUM COLORATUM	A,H	
5079	VISCUM FLAVESCENS	A,H	
5080	VITELLARIA PARADOXA	A,E,H	
5081	VITEX AGNUS-CASTUS	A,E,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5082	VITEX NEGUNDO	A,H	
5083	VITEX ROTUNDIFOLIA	A,H	
5084	VITEX TRIFOLIA	A,H	
5085	VITIS VINIFERA	A,E,H	
5086	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5087	WAHLENBERGIA GRACILIS	A,H	
5088	WALNUT	E	
5089	WALNUT OIL	E	
5090	WATER MELON	E	
5091	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5092	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5093	WHEAT DEXTRIN	A,E	Only for use when the dosage form is capsule, tablet or pill. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5094	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5095	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of Wheat germ glycerides when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5096	WHEAT LEAF	E	
5097	WHEAT SPROUT	E	Gluten is a mandatory component of Wheat sprout when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5098	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of –Wheat Starch. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
5099	WHEATGERM OIL	A,E,H	
5100	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5101	WHEY PROTEIN	E	Lactose is a mandatory component of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			Whey protein when the route of administration is oral.
5102	WHEY PROTEIN CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5103	WHITE BEESWAX	E	
5104	WHITE HOREHOUND HERB DRY	A,H	
5105	WHITE HOREHOUND HERB POWDER	A,H	
5106	WHITE SOFT PARAFFIN	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5107	WIKSTROEMIA VIRIDIFLORA	A,H	
5108	WILD CARROT HERB DRY	A,E,H	
5109	WILD CARROT HERB POWDER	A,H	
5110	WILD CHERRY BARK DRY	A,H	
5111	WILD CHERRY BARK POWDER	A,H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5112	WILD LETTUCE LEAF DRY	A,H	
5113	WILD LETTUCE LEAF POWDER	A,H	
5114	WINTERGREEN OIL	A,E,H	Methyl salicylate is a mandatory component of Wintergreen oil. The concentration of Methyl salicylate in the medicine must be no more than 0.001%. When the concentration of Methyl salicylate in a liquid preparation is more than 5%, and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of Methyl salicylate in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging but the delivery device must be engaged into the container in such a way that prevents it from being readily removed, direct suction through the delivery device results in delivery of no more than one dosage unit, and actuation of the spay device is ergonomically difficult for young children to accomplish.
5115	WITHANIA SOMNIFERA	A,E,H	
5116	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5117	WOOL FAT	A,E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5118	XANTHAN GUM	E	
5119	XANTHIUM SIBIRICUM	A,H	
5120	XANTHIUM STRUMARIUM	A,H	
5121	XANTHOMONA CAMPESTRIS	A,H	
5122	XEROPHYLLUM ASPHODELOIDES	A,H	
5123	XYLENE	E	The residual solvent limit for xylene is 21.7 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.217%.
5124	XYLITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) ‘Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]’.
5125	XYLOSE	E	
5126	YAM	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5127	YARROW HERB DRY	A,H	
5128	YARROW HERB POWDER	A,H	
5129	YEAST AUTOLYSATE	E	
5130	YEAST DRIED	A,E,H	
5131	YELLOW 2G	E	Permitted for use as a colour for topical use.
5132	YELLOW BEESWAX	E	
5133	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5134	YELLOW SOFT PARAFFIN	A,E	Only for use in topical medicines for dermal application. When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5135	YLANG YLANG OIL	A,E,H	
5136	YUCCA BACCATA	A,H	
5137	YUCCA ELATA	A,H	
5138	YUCCA FILAMENTOSA	A,H	
5139	YUCCA GLORIOSA	A,H	
5140	YUCCA WHIPPLEI	A,H	
5141	ZANTHOXYLUM AMERICANUM	A,H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5142	ZANTHOXYLUM BUNGEANUM	A,E,H	
5143	ZANTHOXYLUM CLAVA-HERCULIS	A,H	
5144	ZANTHOXYLUM NITIDUM	A,H	
5145	ZANTHOXYLUM PIPERITUM	A,H	
5146	ZANTHOXYLUM SIMULANS	A,H	
5147	ZEA MAYS	A,E,H	
5148	ZEAXANTHIN	A,E	
5149	ZEIN	E	
5150	ZINC	H	Only for use as an active homoeopathic ingredient. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
5151	ZINC AMINO ACID CHELATE	A,E,H	When used internally, zinc is a mandatory component of zinc amino acid chelate. The concentration of zinc in zinc amino acid chelate must be no more than 30%. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5152	ZINC ASCORBATE	A,E,H	When used internally, zinc is a mandatory component of zinc ascorbate. The percentage of zinc from zinc ascorbate should be calculated based on the molecular weight of zinc ascorbate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication ‘For mineral (may state the mineral) supplementation’ is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			only permitted when the medicine is for oral or sublingual use.
5153	ZINC ASCORBATE MONOHYDRATE	A,E,H	When used internally, zinc is a mandatory component of zinc ascorbate monohydrate. The percentage of zinc from Zinc ascorbate monohydrate should be calculated based on the molecular weight of Zinc ascorbate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
5154	ZINC CHLORIDE	A,E,H	The concentration of zinc chloride in the medicine must be no more than 5%. When used internally, zinc is a mandatory component of zinc

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			chloride. The percentage of zinc from zinc chloride should be calculated based on the molecular weight of zinc chloride. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
5155	ZINC CITRATE	A,E,H	When used internally, zinc is a mandatory component of zinc citrate . The percentage of zinc from zinc citrate should be calculated based on the molecular weight of zinc citrate . When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5156	ZINC CITRATE DIHYDRATE	A,E,H	When used internally, zinc is a mandatory component of zinc citrate dihydrate. The percentage of zinc from zinc citrate dihydrate should be calculated based on the molecular weight of zinc citrate dihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5157	ZINC CITRATE TRIHYDRATE	A,E,H	When used internally, zinc is a mandatory component of zinc citrate trihydrate. The percentage of zinc from Zinc citrate trihydrate should be calculated based on the molecular weight of Zinc citrate trihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5158	ZINC DIASPARTATE	A	When used internally, zinc is a mandatory component of zinc diaspartate and availability is restricted to use as a source of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			relevant mineral only. The percentage of zinc from Zinc diaspartate should be calculated based on the molecular weight of Zinc diaspartate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5159	ZINC GLUCONATE	A,E,H	When used internally, zinc is a mandatory component of zinc gluconate. The percentage of zinc from Zinc gluconate should be calculated based on the molecular weight of Zinc gluconate. When for internal use, the maximum recommended daily dose must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5160	ZINC GLYCINATE	A	When used internally, zinc is a mandatory component of Zinc glycinate and availability is restricted to use as a source of the relevant mineral only. The percentage of zinc from Zinc glycinate should be calculated based on the molecular weight of Zinc glycinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5161	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye. The concentration of zinc lactate in a medicine intended for topical use should be no more than 2%. The concentration of Zinc lactate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%. Zinc lactate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old. Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'.
5162	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
	DIHYDRATE		medicines intended for use in the eye. The concentration of Zinc lactate dihydrate in a medicine intended for topical use should be no more than 2%. The concentration of Zinc lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%. Zinc lactate dihydrate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old. Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'.
5163	ZINC LYSINATE	A	When used internally, zinc is a mandatory component of Zinc lysinate and availability is restricted to use as a source of the relevant mineral only. The percentage of zinc from Zinc lysinate should be calculated based on the molecular weight of Zinc lysinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5164	ZINC METHIONINE SULFATE	A	For topical use, the concentration of zinc sulfate must be no more than 5%. When used internally, zinc is a mandatory component of Zinc methionine sulfate and availability is restricted to use as a source of the relevant mineral only. The percentage of zinc from Zinc methionine sulfate should be calculated based on the molecular weight of Zinc methionine sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5165	ZINC MYRISTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5166	ZINC OXIDE	A,E,H	When used internally, zinc is a mandatory component of zinc oxide. The percentage of zinc from zinc oxide should be calculated based on the molecular weight of zinc oxide. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5167	ZINC PARA-PHENOLSULFONATE	E	The concentration of Zinc para-phenolsulfonate in the medicine must not exceed 5%. When used internally, zinc is a mandatory component of zinc para-phenolsulfonate. The percentage of zinc from zinc para-phenolsulfonate should be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			calculated based on the molecular weight of zinc para-phenolsulfonate.
5168	ZINC STEARATE	E	When used internally, zinc is a mandatory component of Zinc stearate. The percentage of zinc from zinc stearate should be calcuated based on the molecular weight of zinc stearate.
5169	ZINC SUCCINATE	A,E,H	When used internally, zinc is a mandatory component of zinc succinate. The percentage of zinc from Zinc succinate should be calculated based on the molecular weight of Zinc succinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			for oral or sublingual use.
5170	ZINC SULFATE	A,E	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate. The percentage of zinc from Zinc sulfate should be calculated based on the molecular weight of Zinc sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication ‘For mineral (may state the mineral) supplementation’ is only permitted when the medicine is for oral or sublingual use.
5171	ZINC SULFATE HEPTAHYDRATE	A,E	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			heptahydrate. The percentage of zinc from Zinc sulfate heptahydrate should be calculated based on the molecular weight of Zinc sulfate heptahydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5172	ZINC SULFATE HEXAHYDRATE	A,E,H	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate hexahydrate. The percentage of zinc from Zinc sulfate heptahydrate should be calculated based on the molecular

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			weight of Zinc sulfate hexahydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5173	ZINC SULFATE MONOHYDRATE	A,E,H	When the route of administration is topical the concentration of zinc sulfate in the medicine must be no more than 5%. When the medicine is for internal use, zinc is a mandatory component of zinc sulfate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'. The indication 'For mineral (may state the mineral) supplementation' is only permitted when the medicine is for oral or sublingual use.
5174	ZINC VALERATE	H	Only for use as an active homoeopathic ingredient. For internal use, zinc is a mandatory component of Zinc valerate. The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate.
5175	ZINGERONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5176	ZINGIBER OFFICINALE	A,E,H	When for oral use AND the extract ratio is equal to or more than 25:1 OR the equivalent dry weight per dosage unit is equal to OR more than 2g, the medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in Column 2
			- (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine'
5177	ZIZIPHUS JUJUBA	A,H	
5178	ZIZIPHUS JUJUBA VAR. SPINOSA	A,H	
5179	ZIZYPHUS SATIVA	A,H	
5180	ZOSTERA MARINA	A,H	
5181	ZUCCHINI	E	