

# Raw Material Questionnaire

## Allergens and Substances of Concern Information

### Introduction

This questionnaire is developed for raw material suppliers to provide information to manufacturers and sponsors of non-prescription medicines. The questionnaire collects information on allergens, substances of concern and other substances, that may be present within raw materials for which there are Australian regulatory requirements. Use of the questionnaire helps ensure compliance with these requirements.

Complementary Medicines Australia (CMA) and Consumer Healthcare Products Australia (CHP Australia) have jointly developed this questionnaire in consultation with member companies.

### 1. Company and Contact Details

1.1 Company Name:

This document was completed by:

Signature

Name:

Title:

Date:

### 2 Product Information

2.1 Raw Material Code:

Raw Material Name:

### 3 Declarable Substance Information

Substance <sup>1</sup>	Substance used in the manufacture or is a known component of the raw material <sup>2</sup>	Quantity of substance in the raw material <sup>3</sup>	Source and description <sup>4</sup>
<b>Major allergens</b>	Celery derived substances <sup>5</sup>		
	Cereal grain derived substances <sup>6</sup>		
	<b>Crustacean derived substances<sup>7</sup></b>		
	<b>Dairy derived substances<sup>8</sup></b>		
	<b>Egg derived substances<sup>9</sup></b>		
	<b>Fish derived substances<sup>10</sup></b>		
	<b>Gluten</b>		
	Lupin derived substances <sup>11</sup>		
	Mollusc derived substances <sup>12</sup>		
	Mustard derived substances <sup>13</sup>		
	<b>Peanut derived substances<sup>14</sup></b>		
	<b>Pollen<sup>15</sup></b>		
	<b>Propolis</b>		
	<b>Royal jelly</b>		
	<b>Sesame derived substances<sup>16</sup></b>		
<b>Soy derived substances<sup>17</sup></b>			
<b>Sulfites<sup>18</sup></b>			
<b>Tree nut derived substances<sup>19</sup></b>			

<b>Substances of concern</b>	<b>Antibiotics</b> <sup>20</sup>				
	<b>Benzoates</b> <sup>21</sup>				
	<b>Ethanol</b>				
	<b>Hydroxybenzoic acid esters</b> <sup>22</sup>				
	<b>Phenylalanine</b> <sup>23</sup>				
	<b>Potassium</b> <sup>24</sup>				
	<b>Sodium</b> <sup>25</sup>				
	<b>Sorbates</b> <sup>26</sup>				
	<b>Sugars</b>				
	<b>All</b> <sup>27</sup>				
	<b>Galactose</b>				
	<b>Lactose</b>				
	<b>Sugar alcohols</b> <sup>28</sup>				
<b>Tartrazine</b>					
<b>Artificial sweeteners</b>		<b>All</b> <sup>29</sup>			
<b>Aspartame</b>					
<b>Saccharin</b> <sup>30</sup>					
<b>Sucralose</b>					
<b>Other Substances</b>	<b>Colours</b>	Natural <sup>31</sup>			
		Synthetic/nature identical <sup>32</sup>			
	<b>Flavours</b>	Natural <sup>31</sup>			
		Synthetic/nature identical <sup>32</sup>			
	<b>Fragrances</b>	Natural <sup>31</sup>			
		Synthetic/nature identical <sup>32</sup>			

#### Notes:

- Provides a description of the substance classified into three categories - major allergens, substances of concern and other substances. The list of allergens and substances of concern is derived from Schedule 1 of the Therapeutic Goods Administration (TGA) Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines, Food Standards Australia New Zealand (FSANZ) Food Standards Code Standard 1.2.3 Information Requirements - Warning Statements, Advisory Statements and Declarations, European Union Commission Directive 2007/68/EC and US Federal Register Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).  
Substances included in Schedule 1 of the Therapeutic Goods Administration (TGA) Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines are indicated in **bold**.
- Identifies if the substance is an ingredient or used in the manufacture of the raw material (including as a processing aid) or is a known component of an ingredient. A response of yes, no or unknown should be provided for every substance.
- Provides the quantity present of the specified substance. A response should be provided for every substance in the form of a discrete quantity (for example 10 mg/g), a limit (for example not more than 10 ppm), not detected (in this case the limit of detection (LOD) and limit of quantification (LOQ) should also be stated) or Unknown.
- Provides information on the source of the specified substance, for example lecithin derived from soy.
- Includes celeriac, celery seed oil, celery leaf, celery seed and all substances derived from celeriac (*Apium graveolens* var. *rapaceum*) and celery (*Apium graveolens*).
- Includes barley (*Hordeum vulgare*), einkorn (*Triticum boeoticum*, *Triticum monococcum*), emmer (*Triticum dicoccum*), kamut (*Triticum turanicum*), oats (*Avena sativa*), rye (*Secale cereale*), spelt (*Triticum spelta*), triticale (*Triticale hexaploide*), wheat (*Triticum durum*), their hybridised strains and all substances derived from cereal grains.
- Includes chitin, chitosan, crab, crayfish, krill, lobster, prawns, shrimp, and all substances derived from fresh water and marine crustaceans.
- Includes bovine colostrum, bovine lactoferrin, casein, caseinates, hydrolysed milk protein, lactose, lactic acid, milk, whey and all substances derived from dairy.
- Includes egg lecithin, egg albumin, egg yolk, egg white and all substances derived from eggs.
- Includes cod liver oil, fish gelatin, fish oil, isinglass, omega-3 marine triglycerides, omega-3 acid ethyl esters and all substances derived from freshwater fish, marine fish including sharks and diadromous fish.

- 11 Includes Australian sweet lupin (*Lupinus angustifolius*), Andean lupin (*Lupinus mutabilis*), white lupin (*Lupinus albus*), plants in the genus *Lupinus* and all substances derived from lupins.
- 12 Includes green lipped mussel oil, green lipped mussel powder, octopi, oysters, squid, squid oil, concentrated omega-3 marine triglycerides - squid and all substances derived from molluscs.
- 13 Includes mustard seed, mustard seed oil and all substances derived from mustard (*Brassica juncea*), (*Brassica nigra*) and (*Sinapis alba*).
- 14 Includes arachis oil, peanut flour and all substances derived from peanuts (*Arachis hypogaea*).
- 15 Pollen includes plant materials with reasonable cause to suspect pollen is present, such as flowering plant tops that are likely to include pollen, unless it is likely that the pollen has been removed.
- 16 Includes sesame oil, sesame seed and all substances derived from sesame (*Sesamum indicum*).
- 17 Includes lecithin, soy bran, soy fibre, soy isoflavones, soy oil, soy protein, soy sterols, tocopherols and all substances derived from soy (*Glycine max*).
- 18 Includes bisulfites, metabisulfites, potassium metabisulfite, sodium metabisulfite, sodium sulfite, sulfites and sulfur dioxide, including when present as a residue, for example in gelatin.
- 19 Includes almond (*Prunus dulcis*), black walnut (*Juglans nigra*), brazil (*Bertholettia excelsa*), cashew (*Anacardium occidentale*), chestnut (*Castanea sativa*), hazelnut (*Corylus avellana*), macadamia (*Macadamia ternifolia*), pecan (*Carya illinoensis*), pistachio (*Pistacia vera*), walnut (*Juglans regia*) and all substances derived from tree nuts.
- 20 Includes all residual antibiotics.
- 21 Includes benzoic acid and its simple salts, for example calcium benzoate, sodium benzoate and potassium benzoate. More complex esters such as methyl benzoate are not included.
- 22 Includes ethyl hydroxybenzoate, methyl hydroxybenzoate, propyl hydroxybenzoate, sodium ethyl hydroxybenzoate, sodium methyl hydroxybenzoate and sodium propyl hydroxybenzoate. Does not include salicylates.
- 23 Includes substances naturally high in protein, containing phenylalanine, for example aspartame, soy (*Glycine max*) and other legumes in the family Fabaceae, spirulina (*Arthrospira platensis*, *Arthrospira maxima*) and those where the raw material processing causes concentration of phenylalanine content
- 24 Includes potassium ascorbate, potassium chloride, potassium bicarbonate, potassium salts and all substances containing potassium.
- 25 Includes sodium ascorbate, sodium chloride, sodium bicarbonate, sodium salts and all substances containing sodium.
- 26 Includes sorbates such as potassium sorbate and sorbic acid. Does not include polysorbates.
- 27 Includes fructose, galactose, glucose, honey, invert sugar, lactose, maltose, sucrose and all substances defined as monosaccharides and disaccharides.
- 28 Includes erythritol, glycerol, isomalt, lactitol, maltitol, mannitol, polydextrose, sorbitol, xylitol and all substances defined as sugar alcohols.
- 29 Includes aspartame, cyclamates, saccharin, sucralose and all other substances defined as artificial that have a functional role in sweetening.
- 30 Includes saccharin calcium and saccharin sodium.
- 31 Natural substances should meet the definition of natural, as included in 'Therapeutic goods advertising: Ensuring 'natural' claims are not misleading'. This generally includes substances that are derived from a form found in nature (algae, animal, bacteria, fungi, plant, marine or mineral sources), applying outlined 'minimal' processing/manufacturing steps and without chemical identity changes.
- 32 Synthetic substances do not meet the definition of natural, as included in 'Therapeutic goods advertising: Ensuring 'natural' claims are not misleading'. This generally includes synthetically modified substances, such as derivatives or salt forms of a natural substance, and synthesised substances that are nature identical.

## References:

Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines

- <https://www.legislation.gov.au/Search/labels%20non-prescription>

TGA interpretative guidance: Medicine labels: Guidance on TGO 91 and TGO 92

- <https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92>

Therapeutic goods advertising: Ensuring 'natural' claims are not misleading

- <https://www.tga.gov.au/therapeutic-goods-advertising-ensuring-natural-claims-are-not-misleading>

Food Standards Australia New Zealand (FSANZ) Food Standards Code Standard 1.2.3 Information Requirements - Warning Statements, Advisory Statements and Declarations

- <https://www.legislation.gov.au/Search/food%20warning%20advisory>

European Union Commission Directive 76/768/EEC

- <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01976L0768-20120823>

European Union Commission Directive 2007/68/EC

- <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02007L0068-20101231>

US Federal Register Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)

- <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>

## Document Revision

This questionnaire should be updated when any information changes or every three years.

Document Revision History		
Date	Version	Changes
16/01/2012	1	First issue.
4/08/2014	2	Introduction updated to reflect name change from CHC to CMA.
25/06/2018	3	Name Change. Revision to reflect the TGO 92 and associated guidance (Version 1.1) including changes to Risk Analysis Key. Removal of most substances not included in legislation. Division into allergens and other substances of concern.
28/10/2019	4	Removal of risk analysis key used in previous versions and improvement of presentation and usability to reflect TGO 92 and updated TGA guidance. Addition of artificial sweeteners, colours, flavours and fragrances. Introduction updated to reflect name change from ASMI to CHP Australia.