Technical Alert

Consultation: Proposed Changes to Required Advisory Statements for (Registered Complementary) Medicine labels – Menthol and Methyl salicylate

Two sperate consultations are now open on proposed changes to Required Advisory Statements for Registered Complementary Medicines containing menthol and methyl salicylate, **closing on 18 May 2020.**

The TGA is seeking comments from interested parties on the addition of proposed new advisory statements for labels of over the counter (OTC) and registered complementary medicines containing either menthol or methyl salicylate for dermal use, in two separate consultations, for inclusion in the Required Advisory Statements for Medicine labels (RASML).

Please note: The proposed changes apply only to registered medicines. Requirements for menthol and methyl salicylate for listed medicines have already been implemented and are included in the Permissible Ingredients Determination.

There are currently no RASML warning statements for menthol or methyl salicylate. The proposal to include advisory statements for menthol and methyl salicylate in RASML follows previously implemented requirements for advisory statements on labels of listed medicines.

The TGA have provided that RASML cannot and is not intended to capture all required warning statements for all medicines, and that additional warnings may be required for some menthol or methyl salicylate-containing registered medicines depending on the specific nature of the medicine. These can be considered during evaluation of specific medicine registration applications.

How to respond to the consultation

For each substance, the TGA are asking the same question:

> **"Do you support the proposed conditions and wording of the advisory statements? If there are aspects you do not support, please explain why you do not support them. You may make suggestions for alternative wording or additional statements that you think are suitable. You may wish to include an assessment of how the proposed changes will impact on you; that is, what do you see as the likely benefits or costs to you (may be financial or non-financial)."**

To provide your feedback sponsors are invited to click 'Make a submission' on the respective consultation page and include your response using the free text field and/or file upload function.

The consultations **close on 18 May 2020.** Any questions relating to submissions for the TGA should be emailed to rasml@health.gov.au, and questions relating to the consultation(s) can be directed to Sven Johanson (RASML Officer), OTC Medicines Evaluation Section sven.johanson@health.gov.au.

Any identified issues, questions and concerns for CMA with the proposed RASML for menthol or methyl salicylate may be addressed to technical@cmaustralia.org.au

Menthol

The existing warning statements (at Appendix A) required for labels of listed medicines for dermal use containing menthol (Under the *Therapeutic Goods (Permissible Ingredients) Determination*) are consistent with the proposed RASML entries for menthol, listed in the table below.

There are two separate entries proposed for patches (entries 4 & 5), for which two of the warning statements ***are not*** required.

Proposed RASML entries for menthol

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Menthol *(Entry 1 of 5)*	In dermal preparations containing 1% or less, EXCEPT patches	• Avoid contact with eyes.
Menthol *(Entry 2 of 5)*	In dermal preparations containing more than 1 per cent and up to 5 per cent, EXCEPT patches	• Avoid contact with eyes. • If you have sensitive skin, test this product on a small area of skin before applying it to a large area. • If irritation develops, discontinue use.
Menthol *(Entry 3 of 5)*	In dermal preparations containing more than 5 per cent, EXCEPT patches	• Avoid contact with eyes. • If you have sensitive skin, test this product on a small area of skin before applying it to a large area. • If irritation develops, discontinue use. • Contains a high concentration of menthol, which can cause severe skin irritation.
Menthol *(Entry 4 of 5)*	In dermal patches containing more than 1 per cent and up to 5 per cent	• If irritation develops, discontinue use.
Menthol *(Entry 5 of 5)*	In dermal patches containing more than 5 per cent	• If irritation develops, discontinue use. • Contains a high concentration of menthol, which can cause severe skin irritation.

Methyl salicylate

The existing warning statements (at Appendix A) required for labels of listed medicines for dermal use containing methyl salicylate (Under the Therapeutic Goods (Permissible Ingredients) Determination) are consistent with the proposed RASML entries for methyl salicylate, listed in the table below, EXCEPT for the omission of the warning “Contains methyl salicylate”.

The TGA have provided that the warning "Contains methyl salicylate" is only relevant when methyl salicylate is included as an excipient, given that active ingredients are already declared on the label. RASML applies to active ingredients only, unless specifically stated otherwise, and a requirement to declare the presence of methyl salicylate when included as an excipient would be more appropriately captured in Schedule 1 to the Therapeutic Goods Order No. 92 (TGO 92) rather than in RASML. This will therefore be considered in an update to TGO 92.

Proposed RASML entries for methyl salicylate

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Methyl salicylate	In dermal preparations	• Do not use if pregnant or likely to become pregnant. • Do not use in children 6 years of age or less. • Application to skin may increase sensitivity to sunlight. • Avoid prolonged exposure in the sun. • If irritation develops, discontinue use.

Resources

- Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Menthol
- Consultation: Proposed changes to Required Advisory Statements for Medicine Labels (RASML): Methyl salicylate
- *Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2021*
- TGA web page published 2 December 2019: Changes to the label warning statement requirements for menthol & methyl salicylate
- TGA web page: Required Advisory Statements for Medicine Labels (RASML)
- RASML No. 5

Appendix A: Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2021 > Listed Medicines requirements for menthol and methyl salicylate.

Note: The menthol and methyl salicylate requirements below are also included for relevant parent ingredients in the Determination that contain these as mandatory components, e.g. Peppermint oil.

3268	MENTHOL	A, E	When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

3352	METHYL SALICYLATE	A, E	Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration in the medicine must not be 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 if: - the delivery device is 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 spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.