

NATURAL HEALTH PRODUCT

MEDICATED VAPOURS

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

April 29, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s) – Medicinal ingredients

Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	
		Common name(s)	Proper name(s)	Part(s)
<ul style="list-style-type: none"> ▶ (1R,2S,5R)-rel-5-methyl-2-(1-methylethyl)-cyclohexanol ▶ (1RS,2RS,5RS)-(±)-5-methyl-2-(1-methylethyl)cyclohexanol ▶ dl-Menthol 	<ul style="list-style-type: none"> ▶ dl-Menthol ▶ Racemic Menthol 	dl-menthol	N/A	N/A
<ul style="list-style-type: none"> ▶ (1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexanol ▶ (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol ▶ l-Menthol 	<ul style="list-style-type: none"> ▶ l-menthol ▶ Menthol 	l-menthol	N/A	N/A
<i>Eucalyptus globulus</i>	<ul style="list-style-type: none"> ▶ Eucalyptus essential oil ▶ <i>Eucalyptus Globulus</i> Leaf essential oil 	N/A	<i>Eucalyptus globulus</i>	Leaf

References: NHPID 2019.

Table 2. Proper name(s), Common name(s), Source material(s) – Complementary ingredients

Proper name(s)	Common name(s)	Source ingredient(s)
		Common name(s)
<ul style="list-style-type: none"> ▶ (1R,4R)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one ▶ d-Camphor 	<ul style="list-style-type: none"> ▶ (+)-Camphor ▶ Camphor ▶ d-Camphor ▶ Natural camphor 	d-camphor
<ul style="list-style-type: none"> ▶ (1RS,4RS)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one ▶ dl-Camphor 	<ul style="list-style-type: none"> ▶ (+-)-Camphor ▶ dl-camphor ▶ Racemic camphor 	dl-camphor

References: NHPID 2019.

Route(s) of administration

- ▶ Topical
- ▶ Inhalation (indirect)

Note

This monograph excludes vaping products.

Dosage form(s)

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Products containing dl-Menthol, l-Menthol and/or Eucalyptus essential oil

(Provides soothing vapours that) Help(s) to temporarily relieve mild nasal congestion and cough associated with the common cold (EMA 2012; Paul et al. 2010; Lis-Balchin 2006; Bove 2001; Gladstar 1999; Schilcher 1997; Morice et al. 1994; HC 1989).

Note

Camphor alone does not support the above claim. It must be combined with at least 1 of the 2 other medicinal ingredients listed in Table 1 (i.e. menthol and/or eucalyptus essential oil).

Dose(s)

Subpopulation(s)

Children 2 to 11 years, Adolescents 12 to 17 years and Adults 18 years and older.

Quantity(ies)

Table 3. Medicinal Ingredient Doses

Medicinal Ingredients	Doses ^{1,2}
l-Menthol	1 – 16%
dl-Menthol	1 – 16%
Eucalyptus essential oil	1 – 25%

¹The maximum concentrations are supported by the following reference: HC 2013.

²The use of the medicinal ingredients in children is supported by the following references: HC 2013; Paul et al. 2010; Bove 2001; Gladstar 1999; Schilcher 1997.

Table 4. Complementary ingredient Doses (safety only)

Complementary Ingredients	Doses ^{1,2}
d-Camphor	1 – 11%
dl-Camphor	1 – 11%

¹The maximum concentrations are supported by the following reference: HC 2013.

²The use of the medicinal ingredients in children is supported by the following references: HC 2013; Paul et al. 2010; Bove 2001; Gladstar 1999; Schilcher 1997.

Direction(s) for use

All products

- ▶ External use only.
- ▶ Avoid contact with eyes and mucous membranes. Do not use on the face or near the nose or mouth.
- ▶ Do not use with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

For children and adolescents 2-12 years

The product should be handled/applied by adults only.

Products in liquid or semi-solid form (i.e. chest rubs)

Apply thinly and evenly to the chest, up to 3 times per day.

Products in patch forms or vaporizers

Do not use (on skin) for more than 8 hours.

Notes

- ▶ Camphor must not be used in patch forms applied on the skin. This restriction does not apply to patches that are only used on clothing.
- ▶ Patches for children must contain a bittering agent and must not include any flavouring agent.

Duration(s) of use

All products

- ▶ For occasional use only.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days.

Risk information

Caution(s) and warning(s)

All products

- ▶ Keep out of reach of children.
- ▶ Seek urgent medical attention or contact a Poison Control Centre if accidental ingestion occurs.
- ▶ Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen, reoccur or are accompanied by a fever, rash or persistent headache,.

Topical products

Avoid exposure of applied area to the sun.

Contraindication(s)

All products

- ▶ Do not use this product if you are pregnant, breastfeeding, have epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions.
- ▶ Do not use this product if you have broken, irritated, or sensitive skin.

Known adverse reaction(s)

All products

Stop use if hypersensitivity/allergy, rash, burning discomfort, nausea, dizziness and/or headache occur.

Topical products containing menthol

Stop use and get medical help right away if you experience pain, swelling or blistering (HC 2017).



Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database.

Storage conditions

- ▶ Child-resistant packaging/containers should be used (HC 2006).
- ▶ Store in airtight, light-resistant container at room temperature.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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