

## 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 the statements are synonymous. Either term or statement may be selected by the applicant.

**Date** March 7, 2017

#### Medicinal Ingredients

**Table 1: Medicinal ingredients**

Proper name(s)	Common name(s)	Source material(s)
<ul style="list-style-type: none"> <li>• d-Camphor</li> <li>• (1R,4R)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one</li> </ul>	<ul style="list-style-type: none"> <li>• (+)-Camphor</li> <li>• Camphor</li> <li>• d-Camphor</li> <li>• Natural camphor</li> </ul>	As per NHPID <sup>1</sup>
<ul style="list-style-type: none"> <li>• dl-Camphor</li> <li>• (1RS,4RS)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one</li> </ul>	<ul style="list-style-type: none"> <li>• (+)-Camphor</li> <li>• dl-Camphor</li> <li>• Racemic camphor</li> </ul>	As per NHPID
<ul style="list-style-type: none"> <li>• dl-Menthol</li> <li>• (1R,2S,5R)-rel-5-methyl-2-(1-methylethyl)-cyclohexanol</li> <li>• (1RS,2RS,5RS)-(±)-5-methyl-2-(1-methylethyl)cyclohexanol</li> </ul>	<ul style="list-style-type: none"> <li>• dl-Menthol</li> <li>• Racemic Menthol</li> </ul>	As per NHPID
<ul style="list-style-type: none"> <li>• l-Menthol</li> <li>• (1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexanol</li> <li>• (1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol</li> </ul>	<ul style="list-style-type: none"> <li>• l-Menthol</li> <li>• Menthol</li> </ul>	As per NHPID
<i>Eucalyptus globulus</i>	Eucalyptus essential oil	As per NHPID

<sup>1</sup> NHPID: Natural Health Products Ingredients Database

## Quantity(ies)

**Table 2: Acceptable concentrations of the medicinal ingredients**

Common name(s)	Subpopulations	Concentrations <sup>1,2</sup>
d-Camphor/dl-Camphor <sup>3</sup>	Adults, adolescents, and children $\geq 2$ years	1 – 11%
l-Menthol/dl-Menthol	Adults, adolescents, and children $\geq 2$ years	1 – 16%
Eucalyptus essential oil	Adults, adolescents, and children $\geq 2$ years	1 – 25%

<sup>1</sup> The maximum concentrations are supported by the following reference: HC 2013.

<sup>2</sup> The 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.

<sup>3</sup> Camphor must be combined with at least one (1) of the two (2) other medicinal ingredients (i.e. menthol and/or eucalyptus essential oil) in order to support the monographed claim.

## Route(s) of administration

- ▶ Topical
- ▶ Indirect inhalation

## Dosage form(s)

Dosage forms suited for indirect inhalation and/or topical administration include, but are not limited to, liquids, oils, sprays, roll-ons, and patches (i.e. chest rubs, skin patches, clothes patches, vaporizers [including plug-in]).

**Use(s) or Purpose(s)** Statement(s) to the effect of

(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 one (1) of the two (2) other medicinal ingredients listed in Tables 1 and 2 (i.e. menthol and/or eucalyptus essential oil).

**Dose(s)**

**Subpopulation(s)**

Adults, adolescents and children  $\geq 2$  years

**Directions for use** Statement(s) to the effect of

*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 (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 three (3) times per day.

*Products in patch forms or vaporizers*

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

**Note:**

- ▶ 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 of use** Statement(s) to the effect of

*All products*

For occasional use only. For use beyond seven (7) days, consult a health care practitioner.

**Risk information** Statement(s) to the effect of

Caution(s) and warning(s):

*All products*

- ▶ Keep out of reach of children.
- ▶ If accidental ingestion occurs, seek urgent medical attention or contact a Poison Control Centre.
- ▶ If symptoms persist or worsen, reoccur or are accompanied by a fever, rash or persistent headache, discontinue use and consult a health care practitioner.

*Topical products*

Avoid exposure of applied area to the sun.

Contraindication(s):

*All products*

- ▶ If you are pregnant or breastfeeding, do not use this product.
- ▶ If you 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, do not use this product.

Known adverse reaction(s):

*All products*

- ▶ Rashes, burning discomfort, nausea, dizziness and/or headache, have been known to occur; in which case, discontinue use.
- ▶ Hypersensitivity has been known to occur; in which case, discontinue use.

*Topical products containing menthol*

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

**Storage conditions***All products*

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

**Non-medicinal ingredients**

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

## 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.

## References cited

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