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

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>d-Camphor</td>
<td>(+)-Camphor</td>
<td>As per NHPID¹</td>
</tr>
<tr>
<td>(1R,4R)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one</td>
<td>Camphor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d-Camphor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Natural camphor</td>
<td></td>
</tr>
<tr>
<td>dl-Camphor</td>
<td>(+-)-Camphor</td>
<td>As per NHPID</td>
</tr>
<tr>
<td>(1RS,4RS)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one</td>
<td>dl-Camphor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Racemic camphor</td>
<td></td>
</tr>
<tr>
<td>dl-Menthol</td>
<td>dl-Menthol</td>
<td>As per NHPID</td>
</tr>
<tr>
<td>(1R,2S,5R)-rel-5-methyl-2-(1-methylethyl)-cyclohexanol</td>
<td>Racemic Menthol</td>
<td></td>
</tr>
<tr>
<td>(1R,2S,5R)-rel-5-methyl-2-(1-methylethyl)cyclohexanol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>l-Menthol</td>
<td>l-Menthol</td>
<td>As per NHPID</td>
</tr>
<tr>
<td>(1R,2S,5R)-5-methyl-2-(1-methylethyl)cyclohexanol</td>
<td>Menthol</td>
<td></td>
</tr>
<tr>
<td>(1R,2S,5R)-5-methyl-2-(propan-2-yl)cyclohexan-1-ol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eucalyptus globulus</td>
<td>Eucalyptus essential oil</td>
<td>As per NHPID</td>
</tr>
</tbody>
</table>

¹NHPID: Natural Health Products Ingredients Database
Table 2: Acceptable concentrations of the medicinal ingredients

<table>
<thead>
<tr>
<th>Common name(s)</th>
<th>Subpopulations</th>
<th>Concentrations&lt;sup&gt;1,2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>d-Camphor/dl-Camphor&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Adults, adolescents, and children ≥ 2 years</td>
<td>1 – 11%</td>
</tr>
<tr>
<td>l-Menthol/dl-Menthol</td>
<td>Adults, adolescents, and children ≥ 2 years</td>
<td>1 – 16%</td>
</tr>
<tr>
<td>Eucalyptus essential oil</td>
<td>Adults, adolescents, and children ≥ 2 years</td>
<td>1 – 25%</td>
</tr>
</tbody>
</table>

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


References reviewed


