Medicated vapours

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MEDICATED VAPOURS Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 65 KB) 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 ingredient. Notes This monograph excludes vaping products and products which can be inserted in the nostrils. The monograph does not apply to products intended for use on the face or near the nose or mouth (e.g., does not include nasal sprays). Text in parentheses is additional optional information which can be included on the 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 on the label. This monograph cannot be combined with any other monograph at Class II. Date January 10, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information - Medicinal ingredients Proper name(s) Common name(s) Source Information Source ingredient(s) Source material(s) Part(s) (1R,2S,5R)-rel-5-Methyl-2-(1-methylethyl)-cyclohexanol (1RS,2RS,5RS)-(±)-5-Methyl-2-(1-methylethyl) cyclohexanol dl-Menthol dl-Menthol Racemic Menthol dl-Menthol N/A N/A (1R,2S,5R)-5-Methyl-2-(1-methylethyl)cyclohexanol (1R,2S,5R)-5-Methyl-2-(propan-2-yl)cyclohexan-1-ol l-Menthol l-Menthol Menthol l-Menthol N/A N/A N/A Mentha arvensis Herb top flowering Herb top Leaf N/A Mentha canadensis Herb top N/A Mentha x piperita Herb top flowering Leaf Eucalyptus globulus Eucalyptus essential oil Eucalyptus Globulus Leaf essential oil N/A Eucalyptus globulus Leaf Reference: NHPID 2024. Table 2. Proper name(s), Common name(s), Source information - Complementary ingredients Proper name(s) Common name(s) Source information Source ingredient(s) (1R,4R)-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one d-Camphor (+)-Camphor Camphor d-Camphor Natural camphor d-Camphor (1RS,4RS)-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one dl-Camphor (+-)-Camphor dl-Camphor Racemic camphor dl-Camphor Reference: NHPID 2024. Route of Administration Topical and inhalation Inhalation Dosage Form(s) Cream; Emulsion; Foam; Gel; Liniment; Liquid for inhalation; Oil; Ointment; Patch; Plaster; Salve; Spray; Spray, suspension; Vapour from liquid Notes This monograph only supports patch or plaster forms applied on clothing. The route of administration 'inhalation' should be selected for these dosage forms. Patches or plasters for children must contain a bittering agent (e.g. Denatonium benzoate) and must not include any other flavouring agents. 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 2024; 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 of the medicinal ingredients listed in Table 1. Dose(s) Subpopulation(s) Children 2 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older. Quantity(ies) Table 3. Medicinal Ingredient Doses Medicinal Ingredients Doses 1,2 dl-Menthol and/or l-Menthol 1 - 16% Eucalyptus essential oil 1 - 25% 1 Quantities are expressed as percentage weight by weight (% w/w), percentage volume by volume (% v/v) or percentage weight by volume (% w/v). The maximum concentrations are supported by the following reference: HC 2024; US FDA 2023. 2 The use of the medicinal ingredients in children is supported by the following references: HC 2024; Paul et al. 2010; Bove 2001; Gladstar 1999; Schilcher 1997. Table 4. Complementary ingredient Doses (safety only) Complementary Ingredients Doses 1,2 d-Camphor and/or dl-Camphor 1 - 11% 1 Quantities are expressed as percentage weight by weight (% w/w), percentage volume by volume (% v/v) or percentage weight by volume (% w/v). The maximum concentrations are supported by the following reference: HC 2024; US FDA 2023. 2 The use of the medicinal ingredients in children is supported by the following references: HC 2024; Paul et al. 2010; Bove 2001; Gladstar 1999; Schilcher 1997. Direction(s) for use All products Do not use on or near the face. Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn (Pray 2006; APhA 2002). Supervise children when they use this product (Ragucci et al. 2007; Love et al. 2004). Products in liquid or semi-solid dosage form (i.e. chest rubs) Apply thinly and evenly to the chest, up to 3 times per day. Products in patch, plaster, liquid for inhalation, spray, spray, suspension, vapour from liquid forms Do

not use for more than 8 hours per day. Products in patch or plaster forms Use only 1 patch/plaster at a time. Duration(s) of Use Ask 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 For external use only. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010). When using this product avoid contact with the eyes and mucous membranes. If contact occurs, rinse thoroughly with water (US FDA 2023). Stop use and ask 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. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away (CPS 2008; HC 2004). Topical products When using this product avoid exposure of applied area to the sun (HC 2022). Contraindication(s) All products Do not use if you have epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions. Topical products Do not use if you have broken, irritated, or sensitive skin (HC 2022). Known adverse reaction(s) All products Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if hypersensitivity/allergy, skin irritation, nausea and/or dizziness occur (Tisserand and Young 2014). Topical products containing dl-Menthol and/or l-Menthol Stop use and get medical help right away if you experience pain, swelling or blistering, as rare but serious burns can occur (HC 2017). Non-medicinal ingredients Ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database and in the current Cosmetic Ingredient Hotlist, when relevant. Note that essential oils containing menthol or eucalyptol cannot be added as non-medicinal ingredients in a medicated vapours formulation and must be declared as a medicinal ingredients, as they would contribute to the pharmacological effect of the product. Examples of ingredients containing menthol include, Juniperus communis, Mentha arvensis, Mentha canadensis, Mentha pulegium, Mentha spicata, Mentha x piperita and Ocimum basilicum. Examples of ingredients containing eucalyptol (1,8-cineole) include, Cinnamomum camphora, Eucalyptus spp, Laurus nobilis, Lavandula latifolia, Melaleuca alternifolia, Melaleuca cajuputi, Melaleuca quinquenervia, Rosmarinus officinalis and Thymus vulgaris. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations. All products (information for industry; not for labelling) Preserve in tight containers, protected from light (Tisserand and Young 2014). Child-resistant packaging/containers should be used (HC 2004, 2006). 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details.

References Cited APhA 2002: Berardi RR, DeSimone EM, Newton GGD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An interactive approach to self-care. 13th edition. Washington (DC): American Pharmaceutical Association;2002. Bove M. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated;1996. Brinker F. Herb Contraindications and Drug Interactions. 4th edition. Sandy (OR): Eclectic Medical Publications;2010. EMA 2024: European Medicines Agency. European Union herbal monograph on Eucalyptus globulus Labill.; Eucalyptus polybractea R.T. Baker; Eucalyptus smithii R.T. Baker, aetheroleum. [Accessed 2024 April 24]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/draft-european-union-herbal-monograph-eucalyptus-globulus-labill-eucalyptus-polybractea-rt-baker-eucalyptus-smithii-rt-baker-aetheroleum-revision-1_en.pdf Gladstar R. Herbal Remedies for Children's Health. North Adams (MA): Storey Publishing;1999. HC 1989: Health Canada, Third report of the expert advisory committee on non- prescription cough and cold remedies to the protection branch health and welfare Canada: Phenylpropanolamine, lozenges and combinations. [Accessed 2024 March 11]. Available from: http://publications.gc.ca/collections/Collection/H49-157-1989E.pdf HC 2004: Health Canada. It's Your Health: Safe use of Health Products Containing Camphor and/or Eucalyptus Oils. Ottawa (ON): Health Canada; October 2004 [Accessed 2024 April 25]. Available from: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/life-vie/camphor-camphre-eng.pdf HC 2006: Health Canada, Natural and Non-Prescription Health Products Directorate - Labelling Guidance Document [Accessed 2024 March 11]. Available from: https://publications.gc.ca/collections/Collection/H164-24-2006E.pdf HC 2017: Health Canada. Summary Safety Review - Over-the-Counter topical pain relievers containing menthol, methyl salicylate or capsaicin - Assessing the risk of serious skin burns. [Accessed 2024 March 11]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/summary-safety-review-pain-relievers-containing-menthol-methyl-salicylate-capsaicin-risk-serious-skin-surns.html HC 2022: Health Canada, Natural and Non-Prescription Health Products Directorate - Monograph: Aromatherapy [Accessed 2024 March 11]. Available from: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=aromatherap■=eng HC 2024: Health Canada, Natural and Non-Prescription Health Products Directorate - Monograph: Counterirritants. [Accessed 2024 March 11].

Available from: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=counter&amp%3Blang=eng Lis-Balchin M. Aromatherapy Science: A guide for healthcare professionals. London (GB): Pharmaceutical Press;2006. Love JN, Sammon M, Smereck J. Are one or two dangerous? Camphor exposure in toddlers. The Journal of Emergency Medicine 2004;27(1):49-54. Morice AH, Marshall AE, Higgins KS, Grattan TJ. Effect of inhaled menthol on citric acid induced cough in normal subjects. Thorax 1994;49:1024-1026. NHPID 2024: Natural Health Products Ingredients Database. Natural and Non-Prescription Health Products Directorate. [Accessed 2024 April 26]. Available from: http://webprod.hc- sc.gc.ca/nhpid-bdipsn/search rechercheReq.do Paul IM, Beiler JS, King TS, Clapp ER, Vallati J, Berlin CM. Vapor Rub, petrolatum and no treatment for children with nocturnal couch and cold symptoms. Pediatrics 2010;126(6):1092-1099. Ragucci KR, Trangmar PH, Bigby JG, Detar TD. Camphor ingestion in a 10-year-old male. Southern Medical Journal 2007;100(2):204-207. Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (D): Medpharm Scientific Publishers;1997. Tisserand R, Young R. Essential oil safety: A guide for health care professionals, 2nd edition. Edinburgh (GB): Churchill Livingstone;2014. US FDA 2023: United States Food and Drug Administration. Final Administrative Order: Over-the-Counter Monograph M017: External Analgesics Drug Products for Over-the-Counter Human Use (posted May 2, 2023). Code of Federal Regulations. Title 21, Part 348. [Accessed 2024 January 23]. Available from: https://dps.fda.gov/omuf/monographsearch. References Reviewed Battaglia, S. The Complete Guide to Aromatherapy, 2th edition. Brisbane (AU): The International Centre of Holistic Aromatherapy;2004. Price S, Price L. Aromatherapy for Health Professionals, 4th edition. Edinburgh (GB): Churchill Livingstone;2012. Tisserand R, Balacs T. Essential oil safety: A guide for health care professionals. Edinburgh (GB): Churchill Livingstone;1995. Worwood VA. The complete book of essential oils and aromatherapy. Novato (CA): New World Library;1991. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Proper name(s)Common name(s)Source InformationSource ingredient(s)Source material(s)Part(s)
(1R,2S,5R)-rel-5-Methyl-2-(1-methylethyl)-cyclohexanol(1RS,2RS,5RS)-(±)-5-Methyl-2-(1-methylethyl) cyclohexanoldl-Mentholdl-MentholRacemic Mentholdl-MentholN/AN/A(1R,2S,5R)-5-Methyl-2-(1-methylethyl)cyclohexanol(1R,2S,5R)-5-Methyl-2-(propan-2-yl)cyclohexan-1-oll-Mentholl-MentholMentholl-MentholN/AN/AN/A
Mentha arvensisHerb top floweringHerb topLeafN/AMentha canadensisHerb topN/AMentha x piperitaHerb top floweringLeafEucalyptus globulusEucalyptus essential oilEucalyptus GlobulusLeaf essential oilN/AEucalyptus globulusLeaf

DOSAGE FORM(S)

Patches or plasters for children must contain a bittering agent (e.g. Denatonium benzoate) and must not include any other flavouring agents.

DOSE(S)

Medicinal IngredientsDoses1,2 dl-Menthol and/or l-Menthol1 - 16%Eucalyptus essential oil1 - 25%

RISK INFORMATION

Caution(s) and warning(s) All products For external use only.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010).When using this product avoid contact with the eyes and mucous membranes. If contact occurs, rinse

thoroughly with water (US FDA 2023).Stop use and ask 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.Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away (CPS 2008; HC 2004). Topical products When using this product avoid exposure of applied area to the sun (HC 2022). Contraindication(s) All products Do not use if you have epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions. Topical products Do not use if you have broken, irritated, or sensitive skin (HC 2022). Known adverse reaction(s) All products Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if hypersensitivity/allergy, skin irritation, nausea and/or dizziness occur (Tisserand and Young 2014). Topical products containing dl-Menthol and/or l-Menthol Stop use and get medical help right away if you experience pain, swelling or blistering, as rare but serious burns can occur (HC 2017).

NON-MEDICINAL INGREDIENTS

Ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database and in the current Cosmetic Ingredient Hotlist, when relevant. Note that essential oils containing menthol or eucalyptol cannot be added as non-medicinal ingredients in a medicated vapours formulation and must be declared as a medicinal ingredients, as they would contribute to the pharmacological effect of the product. Examples of ingredients containing menthol include, Juniperus communis, Mentha arvensis, Mentha canadensis, Mentha pulegium, Mentha spicata, Mentha x piperita and Ocimum basilicum. Examples of ingredients containing eucalyptol (1,8-cineole) include, Cinnamomum camphora, Eucalyptus spp, Laurus nobilis, Lavandula latifolia, Melaleuca alternifolia, Melaleuca cajuputi, Melaleuca quinquenervia, Rosmarinus officinalis and Thymus vulgaris. Storage conditions Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products (information for industry; not for labelling) Preserve in tight containers, protected from light (Tisserand and Young 2014).Child-resistant packaging/containers should be used (HC 2004, 2006).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products (information for industry; not for labelling) Preserve in tight containers, protected from light (Tisserand and Young 2014).Child-resistant packaging/containers should be used (HC 2004, 2006).

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Table 4. Complementary ingredient Doses (safety only)Complementary IngredientsDoses1,2d-Camphor and/or dl-Camphor1 - 11% 1Quantities are expressed as percentage weight by weight (% w/w), percentage volume by volume (% v/v) or percentage weight by volume (% w/v). The maximum concentrations are supported by the following reference: HC 2024; US FDA 2023.2The use of the medicinal ingredients in children is supported by

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ame(s)	Common name(s)	Source Information	
gredient(s)	Source material(s)	Part(s)	
)-rel-5-Methyl-2-(1-methylethyl)-cyclohexanol	dl-Menthol(1RS,2RS,5RS)-(±)-5-Methyl-2-(1-methylethyl) cyclohexanoldl-Menthol	N/A	
)-5-Methyl-2-(1-methylethyl)cyclohexanol	l-Menthol(1RS,5R)-5-Methyl-2-(propan-2-yl)cyclohexan-1-oll-Menthol	N/A	
	Mentha arvensis	Herb top floweringHerb topLeaf	
	Mentha canadensis	Herb top	
	Mentha x piperita	Herb top floweringLeaf	
s globulus	Eucalyptus essential oilEucalyptus GlobulusLeaf	N/Aessential oil	Eucalyptus globulus

Proper name(s)	Common name(s)	Source information
Source ingredient(s)		
(1R,4R)-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one	(+)-Camphord-CamphorNatural camphor	dl-Camphor
(1RS,4RS)-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one	(±)-Camphordl-CamphorRacemic camphor	dl-Camphor

Medicinal Ingredients	Doses1,2
dl-Menthol and/or l-Menthol	1 - 16%
Eucalyptus essential oil	1 - 25%

Complementary Ingredients	Doses1,2
d-Camphor and/or dl-Camphor	1 - 11%