

Frankincense - Topical

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FRANKINCENSE - BOSWELLIA SACRA - Topical 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 - 47 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 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. Date February 28, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Boswellia sacra Bible frankincense Frankincense Incense Olibanum Olibanum-tree Ru xiang shu Boswellia sacra Stem bark resin References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Source information: PPRC 2020. Route of Administration Topical Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Cream; Liquid; Ointment; Paste; Powder; Salve; Solution; Topical liquid. Use(s) or Purpose(s) Used in Traditional Chinese Medicine (TCM) to help in tissue regeneration/heal minor injuries/sores (PPRC 2020; Bensky et al. 2004). Used in Traditional Chinese Medicine (TCM) to help relieve pain (PPRC 2020; Bensky et al. 2004). Used in Traditional Chinese Medicine (TCM) to help reduce swelling (PPRC 2020; Bensky et al. 2004). Traditionally used in Ayurveda to help treat ringworm (Williamson 2002; Kapoor 2001). Notes The above uses can be combined on the product label if from the same traditional system of medicine (e.g., Used in Traditional Chinese Medicine (TCM) to promote healing of injuries and sores). For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Frankincense is used in Traditional Chinese Medicine (TCM) to help heal minor injuries). When ALL of the same medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). Methods of preparation: Dry, Powdered, Non-Standardized Liquid Extracts (Tincture, Fluid extract, Decoction, Decoction concentrate) 25 - 100% stem bark resin or stem bark resin extract preparation in the finished product (PPRC 2020; Bensky et al. 2004; Chen and Chen 2004). Notes For dry/powder and non-standardized ethanolic extract preparations, a dosage of 3 - 5 grams per day of stem bark resin or stem bark resin equivalent is required (PPRC 2020). For decoction and decoction concentrate, a dosage equivalent to 3 - 10 grams of stem bark resin per day is required (Bensky et al. 2004; Chen and Chen 2004). Products in liquid (Liquid, Solution, Topical liquid) or powder dosage forms must be prepared by the consumer prior to use (see directions for use). Methods of preparation: Non-Standardized Dry Extracts (Extract dry) 1.25 - 100% stem bark resin extract preparation in the finished product (PPRC 2020; Bensky et al. 2004; Chen and Chen 2004). Notes For dry extracts, the extract ratio must be between 1:1 and 20:1. Solvents allowed are water and/or ethanol only. For dry ethanolic extracts, the formulation must provide a quantity equivalent to 1.5 to 2.5 grams stem bark resin per application. For example, for an extract prepared with a 4:1 w/w ratio, the quantity of dry extract in an application must be 375 to 625 mg (1.5 - 2.5 g stem bark resin / 4 w/w (concentration) = 375 - 625 mg dry extract in 1 application. For an application of 1 gram of finished product, the concentration of dry extract (4:1 w/w) in the finished product would be 37.5 - 62.5%. For dry aqueous extracts, the formulation must provide a quantity equivalent to 1.5 to 5 grams stem bark resin per application. For example, for an extract prepared with a 10:1 w/w ratio, the quantity of dry extract in an application must be 375 to 625 mg (1.5 - 5 g stem bark resin / 10 w/w (concentration) = 150 - 500 mg dry extract in 1 application. For an application of 1 gram of finished product, the concentration of dry extract

(10:1 w/w) in the finished product would be 15 - 50%. Direction(s) for use Powder dosage form Prepare as a paste by mixing [insert volume to be measured by consumer in order to provide 1.5-2.5 g of stem bark resin, e.g. ½ teaspoon] of product with a small amount of water until you achieve the desired consistency. Apply to affected area(s), 2 times per day (Bensky et al. 2004; Chen and Chen 2004). Liquid dosage forms (Liquid, Solution, Topical liquid) Soak a small towel/pad/gauze/cotton in [insert volume to be measured by consumer in order to provide 1.5-2.5 grams (ethanolic solutions) or 1.5-5 grams (aqueous solutions) of stem bark resin equivalent, e.g. 2 tablespoons] of the product. Apply on the affected area(s), 2 times per day (Chen and Chen 2004). Cream/Ointment/Paste/Salve dosage forms Apply to affected area(s), 2 times per day (Bensky et al. 2004; Chen and Chen 2004). Products used to help treat ringworm Wash affected area prior to use. Do not bandage. Duration(s) of Use Ask a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use. Risk Information Caution(s) and warning(s) For external use only. When using this product avoid contact with eyes and mucous membranes. If contact occurs, rinse thoroughly with water. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days, or if new symptoms develop. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) Do not use if you are pregnant or breastfeeding. Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. Please note that this organism, one of its parts, or the organism or part from which this ingredient is derived, is considered at risk and is listed in Appendix II of CITES. Details are available from the following reference(s): http://www.ec.gc.ca/cites/default.asp?lang=En&n=C5F64D6F-1#_004. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Bensky D, Clavey, Stöger E, Gamble A. Chinese Herbal Medicine: Materia Medica. 3rd edition. Seattle (WA): Eastland Press, Incorporated; 2004. Chen JK, Chen TT. Chinese Medical Herbology and Pharmacology. Crampton L, editor. City of Industry (CA): Art of Medicine Press Inc.; 2004. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Raton (FL): Taylor and Francis Group; 2013. Kapoor LD. Handbook of Ayurvedic Medicinal Plants. New York (NY): CRC Press; 2001. PPRC 2020: Pharmacopoeia of the People's Republic of China. Volume 1, English edition. Beijing (CN): The State Pharmacopoeia Commission of the People's Republic of China; 2020. USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 June 7]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Williamson EM, editor. Major Herbs of Ayurveda. London (UK): Elsevier Science Limited; 2002. References Reviewed Bensky D, Gamble A. Chinese Herbal Medicine Materia Medica- Revised Edition. Seattle (WA): Eastland Press Inc.; 1986. Bown D. Encyclopedia of Herbs and Their Uses. New York (NY): Dorling Kindersley Limited; 1995. Gruenwald J, Brendler T, Jaenicke C. PDR for Herbal Medicines. Montvale (NJ): Medical Economics Company Inc.; 1998. Leung AY, Foster S. Encyclopedia of Common Natural Ingredients used in Food, Drugs and Cosmetics- 2nd Edition. Toronto (ON): John Wiley and Sons Inc.; 1996. Li SC. Chinese Medicinal Herbs. San Francisco (CA): Georgetown Press; 1973. Long Z. The Chinese Materia Medica. Xue Yuan (China): Academy Press; 1998. Lu H. A Comprehensive Textbook of Chinese Herbology. Vancouver (BC): Academy of Oriental Heritage; 1999. Tierra M, Tierra L. Chinese Traditional Herbal Medicine: Volume 2 Materia Medica and Herbal Resource. Twin Lakes (WI): Lotus Press; 1998. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) For external use only. When using this product avoid contact with eyes and mucous membranes. If contact occurs, rinse thoroughly with water. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days, or if new symptoms develop. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) Do not use if you are pregnant or breastfeeding. Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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. Please note that this organism, one of its parts, or the organism or part from which this ingredient is derived, is considered at risk and is listed in Appendix II of CITES. Details are available from the following reference(s): http://www.ec.gc.ca/cites/default.asp?lang=En&n=C5F64D6F-1#_004. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details.

REFERENCES

Route of Administration Topical

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Boswellia sacra	Bible frankincenseFrankincenseIncenseOlibanumOlibanum treeRu xiang shu	Boswellia sacra	Stem bark resin