PROPOLIS-Topical

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

Note: Text in parentheses is additional optional information which can be included on the Product Licence Application (PLA) and product labels at the applicant's discretion.

Date: January 8, 2014

Proper name(s): Propolis (Lotfy 2006; PPRC 2005)

Common name(s):

- Propolis (Lotfy 2006; PPRC 2005)
- Bee propolis (Lotfy 2006; PPRC 2005)
- Propolis resin (Salatino et al. 2005; Marcucci 1995)

Source material(s): Secretion (of the honey bee *Apis mellifera* L.) (Apidae) (Ramos et al. 2007; Burdock 1998)

Route(s) of administration: Topical

Dosage form(s): Those dosage forms suited to topical administration.

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

Topical	(Traditionally) used in Herbal Medicine to assist in minor wound healing (Lotfy 2006; PPRC 2005; Castalado and Capasso 2002; Peirce 1999; Tilgner 1999).

Dose(s): Preparations equivalent to 0.2-0.6 g propolis, per day (PPRC 2005)

Duration(s) of use: Consult a health care practitioner for use beyond 1 month (Jasprica et al. 2007).

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

Caution(s) and warning(s):

Consult a health care practitioner prior to use if you are allergic to bee products, poplar tree products, or balsam of Peru (Brinker 2001; Marcucci 1995; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Gryzwa 1983).

Consult a health care practitioner if symptoms persist or worsen.

Contraindication(s): No statement required.

Known adverse reaction(s): Hypersensitivity, such as allergy, has been known to occur; in which case, discontinue use immediately (Scully 2006; PPRC 2005; Hsu et al. 2004; Teraki and Shiohara 2001; Machácková 1988; Hausen et al. 1987; Valsecchi and Cainelli 1984; Melli et al. 1983; Rudzki and Grzywa 1983).

Non-medicinal ingredients: Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications: The finished product specifications must be established in accordance with the requirements described in the NHPD Quality of Natural Health Products Guide.
The medicinal ingredient must comply with the requirements outlined in the Natural Health Products Ingredient Database (NHPID).
The medicinal ingredient may comply with the specifications outlined in the Propolis monograph published in the Pharmacopoeia of the People's Republic of China.

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