Health Canada Santé Canada

NATURAL HEALTH PRODUCT

FREE PLANT STEROLS

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 PLA and product 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.

Date June 3, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
Free plant sterols	Free plant sterols	▸ *Arachis hypogaea* ▸ *Brassica napus*	Whole plant
		▸ *Glycine max* ▸ *Gossypium herbaceum* ▸ *Helianthus annuus*	Seed
		▸ *Olea europaea* ▸ *Secale cereal* ▸ *Triticum aestivum* ▸ *Zea mays*	Whole plant

References: Proper name: EC 2002, FDA 2001; Common name: EC 2002, FDA 2001; Source materials: USDA 2019, EC 2002, Kerckhoffs et al. 2002, FDA 2001.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- Helps lower blood total and low density lipoprotein (LDL) cholesterol (Lau et al. 2005, Thomsen et al. 2004, FDA 2001).
- Helps maintain healthy cholesterol levels (Lau et al. 2005, Thomsen et al. 2004, FDA 2001).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

0.74 - 3 grams of Free plant sterols per day, including at least 80 % of Combined beta-Sitosterol, Campesterol and Stigmasterol, per day (FDA 2018, Lau et al. 2005, Thomsen et al. 2004, EC 2002, Kerckhoffs et al. 2002, FDA 2001).

Direction(s) for use

Take with food (FDA 2018, Lau et al. 2005, Thomsen et al. 2004, FDA 2001).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

Contraindication(s)

No statement required.

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

No statement required.

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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