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

February 23, 2024

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 materials(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 information: USDA 2023, 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

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 lower bad 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).

Note: The above uses can be combined on the product label (e.g., Helps lower blood total and low density lipoprotein (LDL) cholesterol and maintain healthy cholesterol levels).

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 2023; Lau et al. 2005; Thomsen et al. 2004; EC 2002; Kerckhoffs et al. 2002; FDA 2001).

Direction(s) for use

Take with food (FDA 2023; Lau et al. 2005; Thomsen et al. 2004; FDA 2001).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Ask a health care practitioner/health care provider/health care professional/doctor/ physician before 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

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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, Labelling of Natural Health Products for more details.

Product Facts	
Medicinal ingredient in each scoop Free plant sterols (*Arachis hypogaea* – whole plant) XX% of combined beta-Sitosterol, Campesterol and Stigmasterol	XX g
Uses • Helps lower blood total and low density lipoprotein (LDL) cholesterol. • Helps lower bad cholesterol • Helps maintain healthy cholesterol levels.	
Warnings	
If applicable[1]: **Allergens: food allergen, gluten (gluten source), sulphites** **Contains aspartame**	
Ask a health care practitioner before use if you are pregnant or breastfeeding**.**	
Directions Adults 18 years and older: • Take X scoop(s), X time(s) a day • Take with food.	
Other information (Add storage information)	
Non-medicinal ingredients List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

[1]This section can be removed from the table if the product contains no allergen or aspartame.

References cited

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