

NATURAL HEALTH PRODUCT

PLANT STEROL ESTERS

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 material(s)	Part(s)
Plant sterol esters	Plant sterol esters	<ul style="list-style-type: none"> • <i>Glycine max</i> • <i>Gossypium herbaceum</i> 	Seed
		<ul style="list-style-type: none"> • <i>Arachis hypogaea</i> • <i>Brassica napus</i> • <i>Olea europaea</i> • <i>Secale cereale</i> • <i>Triticum aestivum</i> • <i>Zea mays</i> 	Whole plant

References: Proper name: FDA 2023, EC 2002, FDA 2001; Common name: FDA 2023, EC 2002, FDA 2001; Source information: USDA 2023, EC 2002, Kerckhoffs et al. 2002, FDA 2001.

Route of administration

Oral (FDA 2023; de Jong et al. 2008; Chen et al. 2005; Davidson et al. 2001; FDA 2001; Clifton et al. 2004; Hendriks et al. 2003; Hendriks et al. 1999; Westrate and Meijer 1998)

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 (FDA 2023; de Jong et al. 2008; Chen et al. 2005; Clifton et al. 2004; Hendriks et al. 2003; Davidson et al. 2001; FDA 2001; Hendriks et al. 1999, Westrate and Meijer 1998).
- Helps lower bad cholesterol (FDA 2023; de Jong et al. 2008; Chen et al. 2005; Clifton et al. 2004; Hendriks et al. 2003; Davidson et al. 2001; FDA 2001; Hendriks et al. 1999, Westrate and Meijer 1998).
- Helps maintain healthy cholesterol levels (FDA 2023; de Jong et al. 2008; Chen et al. 2005; Clifton et al. 2004; Hendriks et al. 2003; Davidson et al. 2001; FDA 2001; Hendriks et al. 1999, Westrate and Meijer 1998).

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)

0.8 – 4.8 grams of Plant sterol esters per day, including at least 80 % of Combined beta-Sitosterol, Campesterol and Stigmasterol, per day (FDA 2023; de Jong et al. 2008; Chen et al. 2005; Clifton et al. 2004; Hendriks et al. 2003; EC 2002; Kerckhoffs et al. 2002; Davidson et al. 2001; FDA 2001; Hendriks et al. 1999; Westrate and Meijer 1998).

Direction(s) for use

Take with food (FDA 2023; de Jong et al. 2008; Chen et al. 2005; Clifton et al. 2004; Hendriks et al. 2003; Davidson et al. 2001; FDA 2001; Hendriks et al. 1999; Westrate and Meijer 1998).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Ask a healthcare 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 ingredients in each scoop	
Plant sterol esters (<i>Glycine max</i> – seed)	XX g
XX % of combined beta-Sitosterol, Campesterol and Stigmasterol	
Uses	
<ul style="list-style-type: none"> • Helps lower blood total and low density lipoprotein (LDL) cholesterol. • Helps lower bad cholesterol. • Helps maintain healthy cholesterol levels 	
Warnings	
If applicable¹:	
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	

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

References cited

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EC 2002: European Commission. General view of the Scientific Committee on Food on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources, with particular attention to the effects on β -carotene. Health & Consumer Protection Directorate-General. [Accessed 2024 February 3]. Available from : https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_out143_en.pdf

FDA 2001: Food and Drug Administration, Department of Health and Human Services. Food labeling: health claims; plant sterol/stanol esters and coronary heart disease. Interim final rule; notice of extension of period for issuance of final rule. Federal Register. 66(109):30311-30313.

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