

Plant Stanol Esters

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Extracted: 2025-08-26T06:35:16.904574

PLANT STANOL ESTERS 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 - 92 K) 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 stanol esters Plant stanol esters Glycine max Gossypium herbaceum Seed Arachis hypogaea Brassica napus Olea europaea Secale cereale Triticum aestivum Zea mays 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; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; FDA 2001) 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; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; FDA 2001). Helps lower bad cholesterol (FDA 2023; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; FDA 2001). Helps maintain healthy cholesterol levels (FDA 2023; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; 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 level). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 1.8 - 5.1 grams of Plant stanol esters per day, including at least 80 % of Combined Sitostanol and Campestanol, per day (FDA 2023; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; EC 2002; Kerckhoffs et al. 2002; FDA 2001). Direction(s) for use Take with food (FDA 2023; de Jong et al. 2008; Hallikainen et al. 2008; Goldberg et al. 2006; Chen et al. 2005; EC 2002; FDA 2001). 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. References Cited Chen JT, Wesley R, Shamburek RD, Pucino F, Csako G. 2005. Meta-Analysis of Natural Therapies for Hyperlipidemia Plant Sterols and Stanols versus Policosanol for Hyperlipidemia. Pharmacotherapy. 25: 171-183. de Jong A, Plat J, Bast A, Godschalk RW, Basu S, Mensink RP. Eur J Clin Nutr. Effects of plant sterol and stanol ester consumption on lipid metabolism, antioxidant status and markers of oxidative stress, endothelial function and low-grade inflammation in patients on current statin treatment. 2008 Feb;62(2):263-273 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 5]. 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. FDA 2023: Food and Drug Administration. § 101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD). [Accessed 2024 February 1]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.83>

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USDA 2023: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. [Accessed 2024 February 1]. Available at: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

References Reviewed Clifton PM, Noakes M, Sullivan D, Erichsen N, Ross D, Annison G, Fassoulakis A, Cehun M, Nestel P. 2004. Cholesterol-lowering effects of plant sterol esters differ in milk, yoghurt, bread and cereal. *European journal of clinical nutrition*. 58: 503-509.

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Lau VW, Journoud M, Jones PJ. Plant sterols are efficacious in lowering plasma LDL and non-HDL cholesterol in hypercholesterolemic type 2 diabetic and nondiabetic persons. *American Journal of Clinical Nutrition*. 2005;81:1351-1358.

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Weststrate JA, Meijer GW. 1998. Plant sterol-enriched margarines and reduction of plasma total- and LDL-cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects. *European journal of clinical nutrition*. 52:334-343.

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MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

DOSAGE FORM(S)

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.

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 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.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Plant stanol esters	Plant stanol esters	Glycine maxGossypium herbaceum	Seed
Arachis hypogaeaBrassica napusOlea europaeaVitis vinifera	Whole plant	Alfalfa plantCerealeTriticum aestivumZea mays	