Vitasterol S-80® Esterified Non GMO

(Mixed phytosterol esters concentrate)

Names

Chemical name: phytosterol esters, plant sterol esters

Identification

This product is a concentrated form of phytosterol esters (mainly Beta-Sitosterol, Campesterol, and Sitostanol). It is obtained by esterification of free plant sterols with fatty acids from vegetable oil.

Name	Empirical formula	Molecular weight	CAS
Mixed phytosterols	Not applicable	≥ 398 - ≤ 417	949109-75-5
Beta-Sitosterol	$C_{29}H_{50}O$	414.72	83-46-5
Campesterol	$C_{28}H_{48}O$	400.69	474-62-4
Stigmasterol	$C_{29}H_{48}O$	412.67	83-48-7
Beta-Sitostanol	$C_{29}H_{52}O$	416.73	83-45-4
Campestanol	$C_{28}H_{50}O$	402.70	474-60-2
Brassicasterol	$C_{28}H_{46}O$	398.67	474-67-9

Standards

This product complies with JECFA and Regulation (EC) Nº 852/2004.
Kosher ("Circle U") and Halal certified. Produced under FSSC 22000 standard.
Non GMO (IP). It is not subjected to be labelled under Regulations (EU) 1829/2003 and 1830/2003.
This product does not contain allergens according to Regulation (EU) Nº 1169/2011 so; it is not required labelling declaration as being potential allergen.
Phytosterol esters are generally recognized as safe (GRAS) by FDA for specific food uses.
This product complies with Commission Implementing Regulation (EU) 2018/1023 concerning Novel Foods and Novel Food Ingredients.

Ingredients/Composition

GC method according to ISO 12228-1:2014

- Sterol Esters: (98 %) min.

Total free sterols and sterol ester content: 99 % min
Total sterols content calculated: 60 % min
Total free sterols content: 2 % max

Sterols Profile:
(According to Commission Implementing Regulation (EU) 2018/1023)

Beta-sitosterol:	< 81 %
Campesterol:	< 40 %
Stigmasterol:	< 30 %
Beta-Sitostanol:	< 35 %
Campestanol:	< 15 %
Brassicasterol:	< 3 %
Other sterols/stanols:	< 3 %

Vitae Caps, S.A.U. (Kensing). C/ Gutenberg 356. Polígono Torrehierro. 45600 Talavera de la Reina. Toledo. Spain.
Tel: +34 925 851013. Web site at: www.kensingsolutions.com. Contact: customercare@kensingsolutions.com

- Mixed tocopherols: 0.05 – 0.2 %
- Ascorbyl palmitate: 0.02 – 0.1%

Quality Control Assay
(Parameters analyzed per batch)

Appearance:	Pale yellow when "liquid" (>45ºC) Creamy white when "oily paste" (Between 10-45ºC) Creamy white when "solid" (<10ºC)
Taste:	Little to none
Odor:	Slightly vegetable oil
Color:	Max. 12 Gardner Units
Viscosity (30ºC):	2400 – 2700 cP
Specific gravity/Density (25ºC):	0.91 – 0.98 g/cm^3
Acidity:	≤ 0.18 ml KOH 0.1N /g (According to ISO 660:2009)
Benzo (a) pyrene:	≤ 2 ppb (As per Commission Regulation (EU) 2023/915)
Sum of Benzo(a)pyrene, Benzo(a)anthracene, Benzo(b)fluoranthene and Chrysene:	≤ 10 ppb (As per Commission Regulation (EU) 2023/915)
Loss on drying:	≤ 4% (In compliance with EP method)
Peroxide Value:	Max. 1 mEqO_2/Kg (Method according to Commission Regulation EEC Nº 2568/91)

(Parameters analyzed periodically based on statistical data)

Heavy metals: Pb: ≤ 0.1ppm Hg: ≤ 0.1ppm Cd: ≤ 1 ppm As: ≤ 3 ppm
(As per Commission Regulation (EU) 2023/915). In compliance with JECFA limits.

Microbiological tests:		
	E. Coli:	None cfu/g
	Salmonella:	None cfu/25g
	Listeria Monocytogenes:	None cfu/25 g
	Shigella:	None cfu/25 g
	Clostridium Perfringens:	None cfu/g
	Staphylococcus Aureus:	None cfu/g
	Enterobacteriaceae:	max 100 cfu/g
	Total Aerobic Count:	max 1000 cfu/g
	Yeast & Moulds:	max 100 cfu/g

(In compliance with EP and Commission Regulation (EC) Nº 2073/2005)

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Sulphated ashes: 0.1% max.
(In compliance with JECFA)

Residual solvents: In compliance with limits established in EP and USP <467> for Class I solvents, JECFA and Directive 2009/32/EC.

Dioxins:
- **Sum of dioxins** (WHO-PCDD/F-TEQ) ≤ 0,75 pg/g fat
- **Sum of dioxins and dioxin-like PCBS** (WHO-PCDD/F-PCB-TEQ) ≤ 1, 25 pg/g fat
- **Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180** (ICES – 6) ≤ 40 ng/g fat

(In compliance with Commission Regulation (EU) 2023/915)

Pesticides: In compliance with Regulation (EC) Nº 396/2005 and amendments.

Properties and Conditions

Solubility: Soluble in hexane, iso-octane and 2-propanol.

Storage: Ambient temperature (max. 30ºC). Protection from light, moisture and air. Store in tightly closed containers.

Shelf life: 18 months from packaging date (unopened).

Packaging: - 20 and 190 kg containers (packaged under nitrogen atmosphere and nitrogen blanketed).
- 1000 L containers (packaged under nitrogen atmosphere).
(In compliance with Commission Regulation (EU) Nº 10/2011)

Labelling: All products produced using "Vitasterol S-80® Esterified Non GMO" may be labelled as "natural source vegetable sterol esters".
The product is in compliance with Regulation (EU) Nº 1169/2011 regarding labelling of foodstuffs and Commission Implementing Regulation (EU) 2018/1023 concerning Novel Foods and Novel Food Ingredients (List of Novel Foods).
Regarding foods and food ingredients with added phytosterol esters, also the Regulation (EU) Nº 1169/2011 should apply.

Foods that contain our "Vitasterol S-80® Esterified Non GMO" can include on their label the following Health Claim (approved under Regulation (EC) Nº 1924/2006): "Plant sterols have been shown to lower/reduce blood cholesterol. High Cholesterol is a risk factor in the development of coronary heart disease". (Only applicable to uses declared in Commission Implementing Regulation (EU) 2018/1023).

Uses: "Vitasterol S-80® Esterified Non GMO" is widely used in food preparations or supplements as LDL cholesterol reducer.
This product has a Health Claim on disease risk approved under article 14 of Regulation (EC) 1924/2006 and Commission Regulations (EC) Nº 983/2009 and 376/2010.

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In Europe, Phytosterols can be added in the food categories stated in the Commission Implementing Regulation (EU) 2018/1023.

FDA has established a Health Claim for Sterol esters and risk of coronary disease (CHD) (21 CFR 101.83).

This product has not been irradiated at any point during the manufacturing process.

Other information

Important: Specific Regulations on the product in the respective countries and for its intended use, have to be observed.

All orders and samples requested will be sent together with an Analysis Certificate and Material Safety Data Sheet. Contact us through our e-mail: customercare@kensingsolutions.com or through our web-site at: www.kensingsolutions.com and your request will be attended to by our local representative.

All information contained here is intended to be accurate. Anyway, this document is provided for your guidance only. We recommend testing the product for your particular purpose, prior to be used in the industrial process.

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