

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 231/2012, E 499 STIGMASTEROL-RICH PLANT STEROLS. (See end of Document for details)

ANNEX

[F¹E 499 STIGMASTEROL-RICH PLANT STEROLS

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| Synonyms | |
| Definition | Stigmasterol-rich plant sterols are derived from soybeans and are a chemically defined simple mixture that comprises not less than 95 % of plant sterols (stigmasterol, β -sitosterol, campesterol and brassicasterol), with stigmasterol representing not less than 85 % of the stigmasterol-rich plant sterols. |
| Einecs | |
| Chemical name | |
| Stigmasterol | (3S,8S,9S,10R,13R,14S,17R)-17-(5-ethyl-6-methyl-hept-3-en-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| β -Sitosterol | (3S,8S,9S,10R,13R,14S,17R)-17-[(2S,5S)-5-ethyl-6-methylheptan-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| Campesterol | (3S,8S,9S,10R,13R,14S,17R)-17-(5,6-dimethylheptan-2-yl)-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| Brassicasterol | (3S,8S,9S,10R,13R,14S,17R)-17-[(E,2R,5R)-5,6-dimethylhept-3-en-2-yl]-10,13-dimethyl-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1Hcyclopenta[a]phenanthren-3-ol |
| Chemical formula | |
| Stigmasterol | C ₂₉ H ₄₈ O |
| β -Sitosterol | C ₂₉ H ₅₀ O |
| Campesterol | C ₂₈ H ₄₈ O |
| Brassicasterol | C ₂₈ H ₄₆ O |
| Molecular weight | |
| Stigmasterol | 412,6 g/mol |
| β -Sitosterol | 414,7 g/mol |

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| Campesterol | 400,6 g/mol |
| Brassicasterol | 398,6 g/mol |
| Assay (products containing only free sterols and stanols) | Content not less than 95 % on a total free sterol/stanol basis on the anhydrous basis |
| Description | Free-flowing, white to off-white powders, pills or pastilles; colourless to pale yellow liquids |
| Identification | |
| Solubility | Practically insoluble in water. Phytosterols and phytostanols are soluble in acetone and ethyl acetate. |
| Stigmasterol content | Not less than 85 % (w/w) |
| Other plant sterols/stanols: either singularly or in combination including Brassicasterol, campestanol, campesterol, Δ -7-campesterol, cholesterol, chlerosterol, sitostanol and β -sitosterol. | Not more than 15 % (w/w) |
| Purity | |
| Total Ash | Not more than 0,1 % |
| Residual Solvents | Ethanol: Not more than 5 000 mg/kg Methanol: Not more than 50 mg/kg |
| Water content | Not more than 4 % (Karl Fischer method) |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 1 mg/kg |
| Microbiological criteria | |
| Total plate count | Not more than 1 000 CFU/g |
| Yeasts | Not more than 100 CFU/g |
| Moulds | Not more than 100 CFU/g |
| <i>Escherichia coli</i> | Not more than 10 CFU/g |
| <i>Salmonella</i> spp. | Absent in 25 g] |

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