Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Palmitoleic acid-rich fatty acid ethyl esters

Name of the ingredient

Palmitoleic acid-rich fatty acid ethyl esters (AIN)

Definition of the ingredient

Ethyl esters of fatty acids obtained by transesterification of the body oil of fish of the families Engraulidae, Carangidae, Clupeidae, Gadidae, Merlucciidae, Osmeridae, Salmonidae and Scombridae or from animals of the class Cephalopoda. The transesterified fatty acids are subjected to subsequent physio-chemical purification processes, including vacuum fractional distillation and urea fractionation.

Contains ethyl esters of palmitoleic acid, minimum 50% w/w. Suitable antioxidants may be added.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Colourless or pale yellow, transparent liquid
Odour	Organoleptic	Slight fish-like odour
Characteristics		
Solubility	BP (General notices)	Practically insoluble in water Very soluble in acetone, ethanol, heptane and methanol

Test	Method reference	Acceptance criteria
Identification		
Chromatogram obtained in the assay of palmitoleic acid ethyl ester	AOCS Ce1b-89	The retention time of the principal peak in the chromatogram of the sample corresponds to that of the principal peak in the chromatogram of the palmitoleic acid ethyl ester reference standard.
Assay		
Palmitoleic acid ethyl ester	AOCS Ce1b-89	Not less than 50 % w/w
Total identified fatty acid ethyl esters (listed in appendix)	AOCS Ce1b-89	Not less than 90 % w/w (calculated as palmitoleic acid ethyl ester)
Unidentified fatty acid ethyl esters	AOCS Ce1b-89	The area of the largest single unidentified peak is not more than 1.5% of the total area. The total area of unidentified peaks as calculated above is not more than 10 %

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual solvents		
Solvent residues	USP <467>	Complies
Incidental metals and non-metals		
While ingredient manufacturers are encouraged to include limits for Incidental metals and non-metals, it is the product into which those substances are formulated that contains the ingredient, alone or in combination with other ingredients, must comply with the acceptance criteria set in the United States Pharmacopeia - National Formulary (USP-NF) general chapter '<2232> Elemental Contaminants in Dietary Supplements'. When testing is performed at the raw material stage, calculation of the total daily exposure in the finished product should be performed. This calculation is based on the quantity of each ingredient present in the product, the maximum potential contamination given the proposed limits for each raw material and the daily dose of the product.		

Test	Method reference	Acceptance criteria
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues	Ph Eur method 2.8.13	Complies
Other organic or inorganic impurities or toxins		
Absorbance	Ph Eur method 2.2.25	Not more than 0.60 at 233 nm
Dioxins, furans and polychlorinated biphenyls (PCBs)	USP monograph for 'Fish oil containing Omega-3 acids'	Complies
Acid value	Ph Eur method 2.5.1 (in 20 g of the substance)	Not more than 2.0
Peroxide value	Ph Eur 2.5.5, method A	Not more than 10.0 meq/kg
Anisidine value	Ph Eur method 2.5.36	Not more than 20.0
Oligomers and partial glycerides	Ph Eur method 2.2.30	Not more than 7.0%
Palmitic acid	AOCS Ce1b-89	Not more than 1.0%
Microbiology		
While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is subject to a legally binding set of criteria. The Therapeutic Goods Order No. 77 *'Microbiological Standards for Medicines'* mandates that any finished product that contains the ingredient, alone or in combination with other ingredients, must comply with the microbial acceptance criteria set by Clause 9 of the Order.		

Key to abbreviations:

AOCS = American Oil Chemist's Society

BP = British Pharmacopoeia

PCBs = Polychlorinated biphenyls

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopoeia

Appendix:

Identified fatty acid ethyl esters

Lauric acid (C12:0, $C_{12}H_{24}O_2$)

Dodecenoic acid (C12:1, $C_{12}H_{22}O_2$)

Tridecanoic acid (C13:0, $C_{13}H_{26}O_2$)

Tridecenoic acid (C13:1, $C_{13}H_{24}O_2$)

Myristic acid (C14:0, $C_{14}H_{28}O_2$)

Myristoleic acid (C14:1, $C_{14}H_{26}O_2$)

Pentadecanoic acid (C15:0, $C_{15}H_{30}O_2$)

Pentadecenoic acid (C15:1, $C_{15}H_{28}O_2$)

Palmitic acid (C16:0, $C_{16}H_{32}O_2$)

Palmitoleic acid (C16:1, $C_{16}H_{30}O_2$)

Hexadecadienoic acid (C16:2, $C_{16}H_{28}O_2$)

Hexadecatrienoic acid (C16:3, $C_{16}H_{26}O_2$)

Hexadecatetraenoic acid (C16:4, $C_{16}H_{24}O_2$)

Heptadecanoic acid (C17:0, $C_{17}H_{34}O_2$)

Margaroleic acid (C17:1, $C_{17}H_{32}O_2$)

Stearic acid (C18:0, $C_{18}H_{36}O_2$)

Oleic acid (C18:1 *cis*-9, $C_{18}H_{34}O_2$)

Vaccenic acid (C18:1 *trans*-11, $C_{18}H_{34}O_2$)

Linoleic acid (C18:2, $C_{18}H_{32}O_2$)

γ-Linolenic acid (C18:3 *n*-6, $C_{18}H_{30}O_2$)

C18:3 (*n*-4) ($C_{18}H_{30}O_2$)

α-Linolenic acid (C18:3 *n*-3, $C_{18}H_{30}O_2$)

Stearidonic acid (C18:4 *n*-3, $C_{18}H_{28}O_2$)

C18:4 (*n*-1) ($C_{18}H_{28}O_2$)

Nonadecanoic acid (C19:0, $C_{19}H_{38}O_2$)

10-Nonadecenoic acid (C19:1, $C_{19}H_{36}O_2$)

10,13-Nonadecadienoic acid (C19:2, $C_{19}H_{34}O_2$)

Arachidic acid (C20:0, $C_{20}H_{40}O_2$)

11-Eicosenoic acid (C20:1, $C_{20}H_{38}O_2$)

Homo-γ-linolenic acid (C20:3 ω-6, $C_{20}H_{34}O_2$)

Eicosatrienoic acid (C20:3 ω-3, $C_{20}H_{34}O_2$)

Arachidonic acid (C20:4 ω-6, $C_{20}H_{32}O_2$)

Eicosatetraenoic acid (C20:4 ω-3, $C_{20}H_{32}O_2$)

Eicosapentaenoic acid (C20:5 *n*-3, $C_{20}H_{30}O_2$)

Heneicosapentaenoic acid (C21:5, $C_{21}H_{32}O_2$)

Behenic acid (C22:0, $C_{22}H_{44}O_2$)

Docosapentaenoic acid (C22:5 *n*-6, $C_{22}H_{34}O_2$)

C22:5 (*n*-3) ($C_{22}H_{34}O_2$)

Docosahexaenoic acid (C22:6 *n*-3, $C_{22}H_{32}O_2$)

Lignoceric Acid (C24:0, $C_{24}H_{48}O_2$)

Nervonic acid (C24:1 *n*-9, $C_{24}H_{46}O_2$)