Australian Government
Department of Health
Therapeutic Goods Administration

Compositional Guideline for DHA/EPA rich *Schizochytrium* algal oil

Name of the ingredient

DHA/EPA rich *Schizochytrium* algal oil (AAN)

Definition of the ingredient

'DHA/EPA rich *Schizochytrium* algal oil' is the winterized, deodorized oil derived from cultivated microalgae *Schizochytrium* sp. Due to taxonomical name changes made to the genus *Schizochytrium*, and for the purposes of this Compositional Guideline, the following genus and species are considered to be included: *Schizochytrium aggregatum, Aurantiochytrium limacinum, Aurantiochytrium mangrovei, Oblongichytrium minutum, Oblongichytrium octosporum*.

It contains docosahexaenoic acid (DHA) at not less than 24% w/w and eicosapentaenoic acid (EPA) at not less than 12% w/w, and the ratio of DHA to EPA is 2:1. Suitable antioxidants may be added.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Light yellow oil
Odour	Organoleptic	Characteristic
Characteristics		
Moisture and Volatiles	AOCS Ca 2c - 25	Not more than 0.02% w/w
Identification		
Fatty acid profile	Ph Eur method 2.4.29	The fatty acid profile is similar to the chromatogram obtained from a authenticated reference material, and meets the requirements below:

Test	Method reference	Acceptance criteria
Palmitic acid (16:0)	Ph Eur method 2.4.29	15.0 - 25.0%
EPA (20:5 n-3)	Ph Eur method 2.4.29	Not less than 14.0%
DPA (22:5 n-3)	Ph Eur method 2.4.29	2.0 - 7.0%
DHA (22:6 n-3)	Ph Eur method 2.4.29	Not less than 28.0%
Assay		
DHA (22:6 n-3) as triglycerides	Ph Eur method 2.4.29	Not less than 240 mg/g
EPA (20:5 n-3) as triglycerides	Ph Eur method 2.4.29	Not less than 120 mg/g

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual solvents	BP (Appendix VIII L and SD IV D)	Complies
Incidental metals and non-metals		
Lead	Ph Eur method 2.4.27	Not more than 0.1 ppm
Arsenic	Ph Eur method 2.4.27	Not more than 0.1 ppm
Cadmium	Ph Eur method 2.4.27	Not more than 0.1 ppm
Mercury	Ph Eur method 2.4.27	Not more than 0.04 ppm
Other organic or inorganic impurities or toxins		
Acid Value	Ph Eur method 2.5.1	Not more than 0.5
Trans Fatty Acids	AOCS Ce 1f - 96	Not more than 1% w/w
Peroxide Value	Ph Eur method 2.5.5 A	Not more than 5

Test	Method reference	Acceptance criteria
Anisidine Value	Ph Eur method 2.5.36	Not more than 20
TOTOX	USP ⟨401⟩	Not more than 26
Unsaponifiable matter	Ph Eur method 2.5.7	Not more than 4.5% w/w
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

DHA = Docosahexaenoic acid

DPA = Docosapentaenoic acid

EPA = Eicosapentaenoic acid

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopeia