Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Compositional Guideline for DHA-rich oil derived from microalgae *Schizochytrium* sp.

Version 2.1, June 2024

Contents

Name of the ingredient

Docosahexaenoic acid (DHA) – rich oil derived from microalgae *Schizochytrium* sp. (AAN)

Definition of the ingredient

DHA-rich oil derived from microalgae *Schizochytrium* sp. is the winterised, deodorised oil derived from cultivated *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 at not less than 350 mg/g. Suitable standardising agents and antioxidants may be added.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Semi-solid to liquid oil, yellow–dark orange colour
Odour	Organoleptic	Characteristic odour
Characteristics		
Moisture and Volatiles	AOCS Ca 2c - 25	≤ 0.05% w/w
Identification		
Fatty acid profile	AOCS Ce 1b – 89	Complies, matches spectrum of authenticated reference material
Assay		
DHA (22:6 n-3)	AOCS Ce 1b – 89 (GC)	≥ 350 mg/g
Free fatty acids	AOCS Ca 5a – 40	≤ 0.25% w/w
Trans fatty acids	AOCS Cd 14 - 95	≤ 1% w/w

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Lead	AOCS Ca 17 – 01	≤ 0.1 ppm
Arsenic	AOCS Ca 17 – 01	≤ 0.1 ppm
Cadmium	AOCS Ca 17 – 01	≤ 0.1 ppm

Test	Method reference	Acceptance criteria
Mercury	AOAC 974.14 and 975.15	≤ 0.04 ppm
Other organic or inorganic impurities or toxins		
Peroxide Value	AOCS Cd 8 – 53	≤ 5 meq/kg
Totox value	USP <401>	≤ 26 meq/kg
Unsaponifiable matter	AOCS Ca 6b – 53	≤ 4.5% w/w
Nitrogen	AOAC 988.05	≤ 0.02%
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: -

AOAC = Association of Analytical Communities

AOCS = American Oil Chemists' Society

GC = Gas chromatography

USP = United States Pharmacopoeia

Version history

Version	Description of change	Author	Effective date
1.0	Original publication	Complementary Medicines Evaluation Section	18/01/2018
2.0	Amendment to change the 'Definition of the ingredient' to include more information about the genus and species	Complementary Medicines Evaluation Section	20/12/2010
2.1	Minor corrections including alignment of the online version with the PDF version of the CG	Complementary Medicines Evaluation Section	3/05/2024

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au

Reference/Publication #