



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

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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	$\leq 4.5\%$ w/w
Nitrogen	AOAC 988.05	$\leq 0.02\%$
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

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Reference/Publication #