



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

### 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
<b>Description</b>		
Appearance	Visual	Semi-solid to liquid oil, yellow-dark orange colour
Odour	Organoleptic	Characteristic odour
<b>Characteristics</b>		
Moisture and Volatiles	AOCS Ca 2c - 25	≤ 0.05% w/w
<b>Identification</b>		
Fatty acid profile	AOCS Ce 1b – 89	Complies, matches spectrum of authenticated reference material
<b>Assay</b>		
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
<b>Incidental metals and non-metals</b>		
Lead	AOCS Ca 17 – 01	≤ 0.1 ppm
Arsenic	AOCS Ca 17 – 01	≤ 0.1 ppm
Cadmium	AOCS Ca 17 – 01	≤ 0.1 ppm
Mercury	AOAC 974.14 and 975.15	≤ 0.04 ppm
<b>Other organic or inorganic impurities or toxins</b>		
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%
<b>Microbiology</b>		
<p>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 <a href="#">Therapeutic Goods Order No. 77 'Microbiological Standards for Medicines'</a> 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.</p>		

**Key to abbreviations**

AOAC = Association of Analytical Communities

AOCS = American Oil Chemists' Society

GC = Gas chromatography

USP = United States Pharmacopoeia