

GENERAL DESCRIPTION

Product name	DHA ΩRIGINS 580 by Fermentalg®
Product code	08103
Description	DHA ΩRIGINS 580 is a refined algal oil extracted from the microalgae <i>Schizochytrium sp.</i> (legal denomination). This foodstuff contains natural omega-3 fatty acids (as triglycerides: TG). DHA ΩRIGINS 580 is suitable for vegetarian diets, is Vegan, Kosher and Halal certified, contains no major allergens and is non-GMO.
Composition	Oil from the microalgae <i>Schizochytrium sp.</i> (FCC - 3204), Mix of natural tocopherols (E306/INS307b)*. *Labelling according to the Chinese regulation: Natural source of Vitamin E (INS 307)
Application	The product is intended for use in dietary supplements and food applications.
Process	DHA ΩRIGINS 580 is produced by a fermentation process and then recovered by physical extraction without the use of organic solvent. The oil is refined. The ingredients used in the formulation of this product are not treated with ionising radiation. In addition, our product is not itself ionised.
Appearance	Clear, pale-yellow oil.
Odor / Flavor	Characteristic and typical of algal oil without rancidity.

SPECIFICATIONS

Chemical properties	Acid Value	Max. 0,50 mg KOH/g	ISO 660*
	Peroxide Value	Max. 5,0 meq O ₂ /kg	AOCS Cd8b-90*
	Anisidine Value	Max. 10,0	European Pharmacopoeia*
	Moisture & Volatiles	Max. 0,05 %	ISO 662*
	Unsaponifiable matter	Max. 3,5 %	External laboratory
	Cold test	Clear	European Pharmacopoeia*
Key fatty acids	Docosahexaenoic acid (DHA)	Min. 580 mg/g (as FA)	European Pharmacopoeia*
	Docosahexaenoic acid (DHA)	Min. 600 mg/g (as TG)	European Pharmacopoeia*
	Eicosapentaenoic acid (EPA)	Min. 3 mg/g (as FA)	European Pharmacopoeia*
	Eicosapentaenoic acid (EPA)	Min. 3 mg/g (as TG)	European Pharmacopoeia*
	Total Omega 3	Min. 583 mg/g (as FA)	European Pharmacopoeia*
	Total Omega 3	Min. 603 mg/g (as TG)	European Pharmacopoeia*
Heavy metals	Arsenic (As)	Max. 0,1 mg/kg (ppm)	External laboratory
	Mercury (Hg)	Max. 0,04 mg/kg (ppm)	External laboratory
	Cadmium (Cd)	Max. 0,01 mg/kg (ppm)	External laboratory
	Lead (Pb)	Max. 0,01 mg/kg (ppm)	External laboratory
Microbiology	Total count (30°C, 72h)	Max. 1000 CFU/g	External laboratory
	Yeasts and molds (25°C, 5d)	Max. 100 CFU/g	External laboratory
	Enterobacteriaceae (37°C)	Max. 100 CFU/g	External laboratory
	Salmonella	Absence /25g	External laboratory
Other contaminants	Trans Fatty Acids	Max. 1,00 g/100g	External laboratory
	PCB (ICES 6)	Max. 10,00 ng/g	External laboratory
	PCDD/F (WHO 17)	Max. 0,75 pg/g	External laboratory
	Sum PCDD/F (WHO 17) + PCB (WHO 12)	Max. 1,25 pg/g	External laboratory
	Total 3-MCPD (free and bound)	Max. 0,400 mg/kg (ppm)	External laboratory
	Glycidyl fatty acid esters expressed as glycidol	Max. 0,200 mg/kg (ppm)	External laboratory
	Benzo(a)pyrene	Max. 1,0 µg/kg	External laboratory
	Sum of benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene	Max. 2,0 µg/kg	External laboratory

*Reference method. As part of its sustainability program, Fermentalg is transitioning to analytical methods that are more environmentally friendly. Alternate methods are only used after Fermentalg has validated the equivalence to the reference method.

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REGULATORY AND GUIDELINES

The product complies with the following:

- Novel Food: Regulation (EU) N° **2017/2470** and N° **2021/1326**
- GOED voluntary monograph Version 8.1 Issue Date January 6, 2022
- Contaminants: Regulation (EU) N° **2023/915**
- Pesticides: Regulation (EC) N° **396/2005** (as amended)
- Microbiological criteria for foodstuffs: Regulation (EC) N° **2073/2005**
- Ingredients list/allergens/nanomaterials: Regulation (EU) N° **1169/2011**
- Plasticizers: Regulation (EC) N° **10/2011** and Regulation (EC) N° **1907/2006**
- GMO labeling: Regulation (EC) N° **1829/2003**
- Irradiation: Directives N° **1999/2/EC** and N° **1999/3/EC**
- Materials: Regulation (EC) N° **1935/2004**
- Code of Federal Regulations (US), 21 CFR 170.3 and 21 CFR 170.30
- USP-NF Monograph "Schizochytrium sp Oil" Issue date May 1, 2018

STORAGE AND USE

The product is guaranteed to meet all product specifications when stored in an unopened original package protected from light and oxygen and for a maximum period of:

- 36 months under frozen storage conditions (<-15°C/5°F),
- 24 months at or below room temperature (25°C/77°F).

Product storage at a temperature <-15°C/5°F is recommended for extended storage and for best sensory performance. Before use, the product must be completely thawed and thoroughly mixed (see document "handling guide"). For best performance, avoid that during the reheating process, the oil temperature exceeds 50°C/122°F for a maximum of 24 hours (e.g.: the thawing time for one drum is 24 hours at a static temperature of 30°C/86°F). As thawing progresses a slight phase shift may occur without negative impact on its quality. It is important to thoroughly mix the contents of the container before use and to maintain adequate agitation during the process at a temperature between 20°C/68°F and 50°C/122°F under protective atmosphere.

We recommend using the entire contents of the drum at one and single time. If an unused product may remain, it must be blanketed quickly after use in its packaging with nitrogen (see document "handling guide") and stored at a temperature <-15°C/5°F.

The product is of natural origin. Due to its nature, the product clarity may vary slightly. During extended storage under refrigerated temperature conditions, semi-solid particles or ingredients may decant in the product without negative impact on its quality. The oil must be thoroughly mixed to resuspend the decantate before use according to the recommendations described in the document "handling guide".

PACKAGING

190 kg steel drums flushed with nitrogen. Other packages are available on request.

DISCLAIMER

All technical data and specifications contained in this document are given for indication purposes only. Fermentalg cannot be held liable for the conditions of use of the product by the client, who shall conduct its own tests, regulatory reviews in order to determine the suitability of the product to each specific need, planned application.

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