

OMEGA-3 OIL



SINCE 1938

Most types of omega-3 fish oils from LYSI are categorised as food supplements. However, the company also offers fish oils to customers as APIs (active pharmaceutical ingredients). Pharmaceutical companies use APIs as the key ingredients in the manufacturing of medicines. LYSI API oils and relevant documents fulfil all requirements made by national regulatory bodies for the registration of medicines.

Omega-3 fish oil is a complex mixture of triacylglycerols (also called triglycerides), which is characterised with an exceptionally high level

of EPA and DHA, or with the approximate ratio 18/12. Omega-3 fish oil is commonly called 18/12 fish oil. It is a **natural** triglyceride oil, containing the highest level of the omega-3 fatty acids.

Omega-3 fish oil is extracted by physical means from fresh fish of the families *Engraulidae*, *Carangidae*, *Clupeidae*, *Osmeridae*, *Scombridae* (except the genera *Thunnus* and *Sarda*) and *Ammodytidae*. The principal species are Peruvian anchoveta (*Engraulis ringens*), European pilchard (*Sardina pilchardus*) and anchovy (*Engraulis encrasicolus*).



LYSI imports crude oil from producers in Peru, Chile and Morocco for processing in the company's refinery in Reykjavik, Iceland. The oil from Peru and Chile is derived from fish caught in the Southeast Pacific Ocean (FAO fishing area 87), whereas the Moroccan oil is extracted from fish caught in the Eastern Central Atlantic Ocean (FAO fishing area 34).

The fishing stocks are under strict government control to ensure sustainability. All producers in Peru and Chile are certified under the IFFO RS programme and many of them offer oil that is certified sustainable by Friend of the Sea (FOS). The oil from Morocco is FOS certified.

LYSI is a major producer of omega-3 fish oil, with a market share of approximately 10% for fully refined omega-3 fish oil.



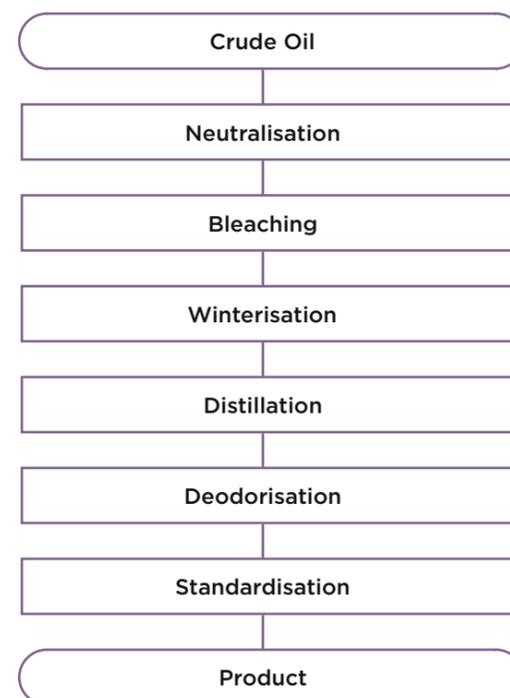
The Refining Process

Crude omega-3 fish oil is not suited for direct consumption and must be refined before use. The refining process removes unwanted components such as free fatty acids, pigments, contaminants and various other substances that can impart fishy flavour or off-flavour to the oil.

The refining process of omega-3 fish oil is comprised of 5 or 6 steps, as outlined below. Distillation (short-path) is not always called for.

It is imperative that the products we consume are clean and that they meet the most stringent international demands issued by health authorities. This is secured through elaborate and comprehensive production processes in the LYSI refinery. The equipment used for refining is custom-made, built on the extensive knowledge of fish oil refining obtained over the last 80 years. The key processes have been validated and approved.

The company is **ISO 9001 certified** and **GMP approved**. LYSI is expecting **FSSC 22000 certification** in June 2017 to replace the current **BRC certification**. FSSC 22000 is fully recognised by the Global Food Safety Initiative (GFSI).



Properties of Omega-3 Fish Oil

As the name implies, omega-3 fish oil is an excellent source of the omega-3 fatty acids EPA and DHA. It is natural fish oil that has not been subjected to any chemical alterations, only refining. The oil may be taken orally as a liquid or in capsule form.

EPA and DHA acids are often considered essential due to their low conversion efficiency from alpha-linolenic acid. They have been extensively studied for the last three decades and their different effects on the body have been described.

Initial studies on the physiological effects of long-chain omega-3 fatty acids focused on the relationship between EPA and DHA and cardiovascular disease. The findings showed that both the acids reduced the risk of cardiovascular disease (Casula, et al., 2013) (de Oliviera Otto, et al., 2013) (Zock, et al., 2016).

A deficiency of omega-3 fatty acids has been implicated as a risk factor in mental disorders such as depression, schizophrenia and ADHD (McNamara, 2016) (Parletta, et al., 2016) (Königs & Kiliaan, 2016).

Technical Aspects

The composition of omega-3 fish oil is defined in the European Pharmacopoeia and the USP, as is shown in the table below:

Omega-3 fish oil from LYSI meets both pharmacopoeias. Vitamins, flavourings and antioxidants can be added in accordance with the needs of the individual customers.

Every batch of omega-3 fish oil produced at LYSI is analysed per specification. The batch is released by QC only when it meets the specification. A certificate of analysis is issued for every batch.

Parameters:	Specification		Typical LYSI values
	Ph.Eur. (Type I)	USP	
EPA (weight % as triglycerides)	min. 13	-	16.0-17.5
EPA (weight % as free acids)	-	min. 13.0	15.5-17.0
DHA (weight % as triglycerides)	min. 9	-	10.5-12.0
DHA (weight % as free acids)	-	min. 9.0	10.0-11.5
Total omega-3 (weight % as triglycerides)	min. 28	-	34.0-36.5
Total omega-3 (weight % as free acids)	-	min. 28.0	32.5-35.0
Acid value (mg KOH/g)	max. 0.5	max. 3	less than 0.1
Unsaponifiable matter (%)	max. 1.5	max. 1.5	less than 1.5
Absorbance at 233 nm	max. 0.70	max. 0.70	0.2
Cold test; remains clear at 0°C (hours)	min. 3	min. 3	> 3
Peroxide value (meq. O ₂ /kg)	max. 10.0	max. 5.0	less than 2.5
Anisidine value	max. 30.0	max. 20.0	10-15
TOTOX	-	max. 26	12-20
Oligomers (%)	max. 1.5	-	0.4

Omega-3 polyunsaturated fatty acids have been shown to contain anti-inflammatory properties. These acids play a role in arthritis and possibly other conditions associated with inflammation (Yates, et al., 2014) (Calder, 2015) (Khatib, et al., 2016).

A number of guides for recommended daily intake of EPA and DHA have been published, with values ranging from 250 mg EPA+DHA/day to 2000 mg total omega-3/day. Typical values for adults are 500 mg/day of EPA+DHA. LYSI omega-3 fish oil normally contains 270 mg EPA+DHA/g.

Product Groups

Fully refined omega-3 fish oil is produced to fulfil LYSI many different specifications. The specifications can be generic or they can be determined in agreement with customers in terms of individual requirements.

Other ingredients can be added, such as vitamins, antioxidants and flavourings. Mixed tocopherols are used as antioxidants. Flavours include lemon, orange, lemon-mint, and tutti-frutti.

All ingredients/additives must be non-GMO, non-irradiated and preferably, Halal-certified.

LYSI also offers various fish oil blends containing omega-3 fish oil. Again, the specifications can be generic or agreed to with customers. Omega-3 fish oil blends must contain at least 51% of omega-3 fish oil to legitimately bear the name Omega-3 fish oil, however, the oil is often used at a lower ratio.

The products are packed into steel drums, IBCs, tankcontainers or flexicontainers, all according to customer requirements.

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