

PronovaPure® 400:200 EE

Valid for batches produced from January 2014

Chemical names of active ingredient

Omega-3 Fatty Acids

Eicosapentaenoic acid (EPA)

Docosahexaenoic acid (DHA)

CAS-No.

86227-47-6 EPA ethyl ester

81926-94-5 DHA ethyl ester

PRD-No.

30593641

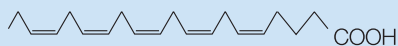
Articles

50355409* 190 kg steel drum

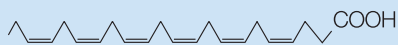
* packed under inert gas

Country of origin

Norway



Eicosapentaenoic Acid EPA



Docosahexaenoic Acid DHA

Description

PronovaPure® 400:200 EE is a light yellow fish oil ethyl ester concentrate.

The fish oil is obtained from anchovies, sardines and mackerels (families Engraulidae, Clupeidae, Scombridae and Carangidae). The product is an ethyl ester (EE), rich in omega-3 fatty acids. The content of EPA (Eicosapentaenoic acid expressed as EE) and DHA (Docosahexaenoic acid expressed as EE) is min. 600 mg/g.

Composition

Ingredients in descending order of weight:
Fish oil ethyl ester concentrate, tocopherol-rich extract* (E 306).
* mainly derived from soybean (from identity preserved, not genetically modified origin)

Solubility

Practically insoluble in water, very soluble in acetone, in ethanol (96 per cent), in heptane and in methanol.

Specification

Assay

as ethyl ester Ph. Eur. 2063/2.4.29	
EPA (Eicosapentaenoic acid)	min. 400 mg/g
DHA (Docosahexaenoic acid)	min. 200 mg/g
EPA & DHA (Eicosapentaenoic & Docosahexaenoic acid)	600 – 700 mg/g
Total Omega-3 content	min. 650 mg/g

as free fatty acid Ph. Eur. 2063/2.4.29	
EPA (Eicosapentaenoic acid)	min. 365 mg/g
DHA (Docosahexaenoic acid)	min. 184 mg/g

For further information see separate document: “Standard Specification” (not for regulatory purposes) available via BASF’s WorldAccount: <https://worldaccount.basf.com> (registered access).

Standards

Produced under cGMP and HACCP principles.

Monographs and Regulations

PronovaPure® 400:200 EE meets the requirements for an omega-3 fatty acid source in most countries. The product complies with the Ph. Eur. monograph on Omega-3-acid ethyl esters 60 (2063). Further, the product conforms to the voluntary GOED monograph in the current version. Fish oil ethyl ester concentrates are accepted for use in dietary supplements in most countries. However, specific regulations on the product and its ingredients in the respective countries and for its intended use have to be observed.

Stability, Storage and Handling

Stored in its unopened original packaging at ambient conditions (0 – 25 °C), the product is stable for at least 36 months. The product is sensitive to oxygen, light and heat. It should therefore be stored in the tightly sealed, lightproof packaging in a cool place. Once opened, it is recommended to use the remaining contents as quickly as possible.

Applications

Dietary supplements:
PronovaPure® 400:200 EE is intended for use in dietary supplements such as in soft gel capsules.

Note

PronovaPure® 400:200 EE must be handled in accordance with the Material Safety Data Sheet.

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May 2015