Technical Information

Maxomega™ EPA 96 EE
Maxomega™ EPA 97 EE

Ethyl Icosapentate (JP)

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1. Introduction

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are oils containing a minimum of 96% of the primary omega-3 acid eicosapentaenoic acid (EPA) in ethyl ester (EE) form.

Omega-3 fatty acids, in general, are naturally occurring nutrients that are of high importance for human health. They cannot be synthesized by the human body but are vital for normal metabolism. Omega-3 fatty acids are poly unsaturated fatty acids with a double bound from the 3rd carbon atom from the end (omega). The most abundant omega-3 fatty acids are EPA, docosahexaenoic acid (DHA) and alfa-linoleic acid (ALA). EPA and DHA are long-chain fatty acids found in algal oil and fish. EPA and DHA have been widely studied for medical and nutritional applications.

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are equivalent products, but with slightly different specifications as they are intended for different markets with different requirements. They are produced the same way from crude fish oil by a transesterification step from a triglyceride to an ethyl ester compound and several concentration and purification steps including liquid chromatography and silica refining. The fish oil is sourced from body oil of wild fatty fish.

The only additional ingredient to EPA EE is the antioxidant alfa tocopherol, which is added in a concentration of approximately 0,2%. The minor part (3-4%) that are not EPA EE consists of other naturally occurring fatty acids, including other omega-3 fatty acids.

Due to the high amount of unsaturated fatty acids, the product will easily oxidize in contact with air, and needs to be protected from contact with oxygen. The container is therefore flushed with nitrogen prior to, during and after filling.

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are used as active ingredients in pharmaceutical preparations for oral application after approval by the concerned medicinal authority for a defined indication.

2. Description

Name

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE

United States Adopted Names (USAN)

Icosapent ethyl

International nonproprietary name (INN)

Icosapent ethyl

Pharmacopeia name

Ethyl Icosapentate (JP)

Chemical names

5Z,8Z,11Z, 14Z, 17Z)-Eicosa-5,8,11,14,17-Pentaenoic Acid Ethyl Ester, Eicosapentaenoic acid etyl ester, Timnodonic acid ethyl ester, Ethyl-EPA

CAS-No

EPA EE 86227-47-6

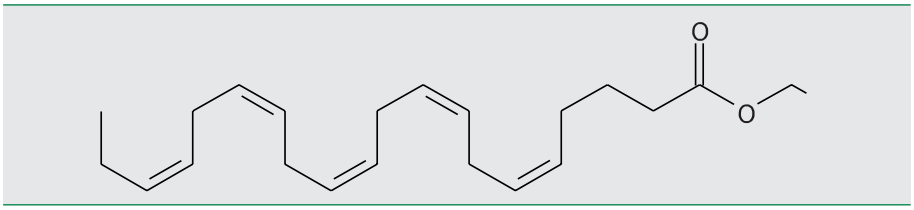
Molecular formula

EPA EE $C_{22}H_{34}O_2$

Relative Molecular mass

EPA EE 330.5

Structural formula



EPA EE

3. Physical and chemical properties

Appearance

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are clear, colourless to pale yellow liquid oils.

Solubility

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are practically insoluble in water, very soluble in organic solvents such as hexane, acetone, ethanol, and methanol.

Boiling point	417.0 + 34.0 °C at 760 Torr
Flash point	103.1 + 24.0 °C
Vapour pressure	3.65E-7 Torr at 25 °C
Enthalpy of Vaporization	67.04 + 3.0 kJ/mol at 760 Torr

4. Medical information

Applications

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are active pharmaceutical ingredient oils. For application, they are typically filled into soft gelatin capsules as the sole fill ingredient. This dosage form is suitable for EPA EE because it protects the API from oxygen and masks taste and odour. As a consequence, EPA EE is not suitable for liquid multidose formulations as it will readily oxidize in contact with atmospheric oxygen, and also has an unpleasant taste and odour.

Therapeutic indication

Maxomega™ EPA 96 EE and Maxomega™ EPA 97 EE are used as active ingredients for the documented indication in pharmaceutical drug products after approval by the competent authority. The approved indications may be different in different countries.

Please refer to the approved indications for finished products containing Ethyl Icosapentate/ Icosapent ethyl in the concerned market.

Clinical Pharmacology
Mechanism of Action

The mechanisms of action for EPA are likely multi-factorial.

Please refer to the approved Summary of Product Characteristics (SmPC) /Full Prescribing Information for finished products containing Ethyl Icosapentate/ Icosapent ethyl.

Pharmacokinetics

Absorption:

After oral administration, EPA EE is de-esterified during the absorption process and the active metabolite EPA is absorbed in the small intestine and enters the systemic circulation mainly via the thoracic duct lymphatic system.

Please refer to the approved Summary of Product Characteristics (SmPC) /Full Prescribing Information for finished products containing Ethyl Icosapentate/ Icosapent ethyl.

5. Handling & Safety

Please refer to the individual material safety data sheet (MSDS) for instructions on safe and proper handling and disposal. Material safety data sheets are sent with every consignment or can be requested from your BASF sales representative

Re-test period & Storage Conditions

Please refer to the document “Quality & Regulatory Product Information” which is available in RegXcellence (RegXcellence (basf.com)).

Packaging

The commercial product is filled in epoxy phenolic lined mild steel drum. The liner contains iron oxide and titan dioxide pigments and have a golden brown colour. The closure is made of the same material. The product is stored under nitrogen atmosphere to prevent oxidation. The external surface is blue.

6. Product specifications

The current version of the product specifications are available at RegXellence (RegXcellence (basf.com)) or from your BASF sales representative.

7. Regulatory & Quality

Please refer to the document Quality & Regulatory Product Information which is available in RegXcellence (RegXcellence (basf.com)).

PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30572258	Maxomega™ EPA 96 EE	50306243 (sample)	0,1 kg aluminum bottle
		50356278	190kg steel drum
30572259	Maxomega™ EPA 97 EE	50306248 (sample)	0,1 kg aluminum bottle
	For the Japanese market only	50305109	190kg steel drum

* BASF’s commercial product number.

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