
Technical Information

Omega-3-acid ethyl esters (K85EE)

Omega-3-acid ethyl esters 90 (Ph.Eur)

Omega-3-Acid Ethyl Esters (USP)

1. Introduction

In general, Omega-3 fatty acids are naturally occurring nutrients that are important 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 bond from the 3rd carbon atom from the end (omega). The most abundant omega-3 fatty acids are EPA, 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. K85EE is produced from the body oil of certain species of wild, fatty fish. The manufacturing process includes a transesterification step from a triglyceride to an ethyl ester compound and several concentration and purification steps, including molecular distillation.

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.

2. Technical properties

Composition

Omega-3 acid ethyl esters (K85EE) is an oil containing a minimum of 90% of omega-3 acid ethyl esters, comprised of 85% of two unsaturated fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in ethyl ester (EE) form. The only ingredient added to K85EE is the antioxidant alpha tocopherol. The remaining part of the composition is comprised of other, naturally occurring fatty acids.

K85EE fully complies to the monographs of the European Pharmacopeia and the US Pharmacopeia.

Description

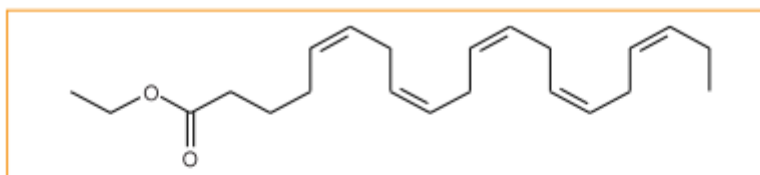
Name	K85EE®
United States Adopted Names (USAN)	Omega-3-acid ethyl esters
Pharmacopeia name	Omega-3-acid ethyl esters 90 (Ph.Eur) Omega-3-Acid Ethyl Esters (USP)

Nomenclature of the two main components	EPA ethyl ester	DHA ethyl ester
Pharmacopeia name	Ethyl Icosapentate (JP) Eicoapentaenoic acid ethyl ester (USP)	Docosahexaenoic acid ethyl ester (USP)
International nonproprietary	Icosapent ethyl ester	Doconexent ethyl ester
United States Adopted Names (USAN)	Icosapent ethyl	N/A
Chemical names	Ethyl all cis-5,8,11,14,17-	Ethyl all cis-4, 7,10,13,16, 19-

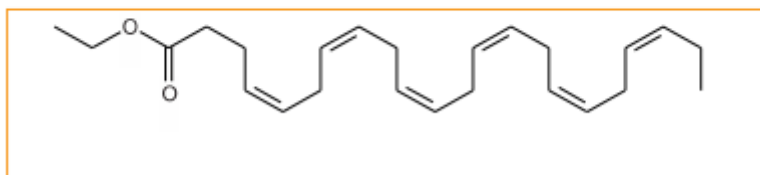
	Eicosapentaenoate	Docosahexaenoate
Trivial names	Timnodonic acid ethyl ester	Cervonic acid ethyl ester
Synonyms	Eicosapentaenoic acid ethyl ester, Ethyl-EPA, C20:5n-3 ethyl ester, EPA EE	Docosahexaenoic acid ethyl ester, Ethyl-DHA, C22:6n-3 ethyl ester, DHA EE
CAS-No	86227-47-6	81926-94-5
Molecular formula	C ₂₂ H ₃₄ O ₂	C ₂₄ H ₃₆ O ₂
Relative Molecular mass	330.50	356.54

Secondary components	USP	UPAC	Nomeric Notation	CAS-number
Octadecatrienoic acid EE	Alpha-linolenic acid ethyl ester	Ethyl all cis-9, 12, 15-Octadecatrienoate	C18:3n-3	1191-41-9
Octadecatetraenoic acid EE	Moroxic acid ethyl ester	Ethyl all cis-6, 9, 12, 15-Octadecatetraenoate	C18:4n-3	119798-44-6
Eicosatetraenoic acid EE	Eicosatetraenoic acid ethyl ester	Ethyl all cis-8, 11, 14, 17-Eicosatetraenoate	C20:4 n-3	123940-93-2
Heneicosapentaenoic acid EE	Heneicosapentaenoic acid ethyl ester	Ethyl all cis-6, 9, 12, 15, 18-Heneicosapentaenoate	C21:5 n-3	131775-86-5
Docosapentaenoic acid EE	Docosapentaenoic acid ethyl ester (Clupanoponic acid ethyl ester)	Ethyl all cis-7, 10, 13, 16, 19-Docosapentaenoate	C22:5 n-3	119818-40-5

Structural formula



EPA EE



DHA EE

3. Physical and chemical properties

Appearance

Omega-3 acid ethyl esters (K85EE) is a clear, light yellow liquid oil.

Solubility

Omega-3 acid ethyl esters (K85EE) is practically insoluble in water, very soluble in organic solvents such as acetone, ethanol (96%), methanol and heptane.



Freezing point	< - 20°C
Boiling point	> 400 °C
Flash point	> 95°C
Vapour pressure	Negligible
Density	0.9 g/ml (20°C)

4. Medical information

Applications

K85EE is an active pharmaceutical ingredient oil. It is well suited for soft gelatin capsules and can be used as the sole fill ingredient. This dosage form has proven suitable for K85EE. K85EE 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

K85EE is used as an active ingredient in pharmaceutical drug products after approval of the documented indication by the competent authority. The approved indications may be different in different countries.

Please refer to the indication in the approved Summary of Product Characteristics (SmPC) / Full Prescribing Information for the finished drug products containing Omega-3 acid ethyl esters for the concerned market.

Clinical Pharmacology

Mechanism of Action

The mechanisms of action of K85EE are not completely understood. The mechanisms are likely multi-factorial. Please refer to the approved Summary of Product Characteristics (SmPC) / Full Prescribing Information for finished drug products containing Omega-3 acid ethyl esters.

Pharmacokinetics

Please refer to the approved Summary of Product Characteristics (SmPC) / Full Prescribing Information for finished drug products containing Omega-3 acid ethyl esters.

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

6. Product specifications

The current version of the product specifications is available at [RegXcellence® \(Home \(force.com\)\)](#) or from your BASF sales representative.

7. Regulatory & Quality

Please refer to the document Quality & Regulatory Product Information which is available in [RegXcellence® \(Home \(force.com\)\)](#).

8. PRD and Article numbers

PRD-No.	Product name	Article	Packaging	Sales region
30593625	K85EE	50355167	190kg steel drum	Europe and those accepting CEP*
30593626	Omega 3 fatty acid ethyl ester	50355168	190kg steel drum	Only for Italy
30593627	K85EE Omega-3-acid ethylesters	50355169	190kg steel drum	USA
30593631	K85EE Omega-3-acid ethylesters	50355400	190kg steel drum	Only for Japan
30593633	K85EE Omega-3-acid ethylesters	50355403	190kg steel drum	Global, except US and Japan

*Certification of Suitability of the monograph of the European Pharmacopeia

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