Technical Information

Maxomega DHA 95 EE AS

Docosahexaenoic acid ethyl ester

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1. Introduction

Maxomega DHA 95 EE AS is an oil containing minimum 95% of the primary omega-3 acid, docosahexaenoic acid (DHA) 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 polyunsaturated fatty acids with a double bound from the 3rd carbon atom from the end (omega). The most abundant omega-3 fatty acids are eicosapentaenoic acid (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 DHA 95 EE AS is produced from algal oil by several concentration and purification steps including liquid chromatography and silica refining. The algal oil is sourced from the micro organism *Schizochytrium sp.*

The only additional ingredient to DHA EE is the antioxidant dl-alpha tocopherol which is added in a concentration of approximately 0,2%. The minor part (4-5%) that is not DHA EE, consists of other naturally occurring fatty acid in ethyl ester form, 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 with DHA 95 EE.

Maxomega DHA 95 EE AS or the genric substance Docosahexaenoic acid ethyl ester has no approved medical indication, but is under development and testing whithin pharmaceutical applications.

DHA at lower concentrations sourced from fish or algae are used in nutritional products, either in ethyl ester or triglycerides form.

2. Description

Name

Maxomega DHA 95 EE AS

United States Adopted Names (USAN)

NA

International nonproprietary name (INN)

Doconexent ethyl

Pharmacopeia name

NA

Chemical names

Ethyl all cis-4, 7,10,13,16, 19-Docosahexaenoate, Docosahexaenoic acid ethyl ester

Cervonic acid ethyl ester, Ethyl-DHA, DHA EE, C22:6n-3 ethyl ester

CAS-No

81926-94-5

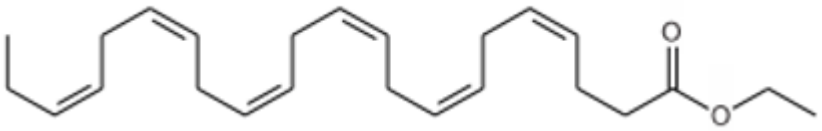
Molecular formula

$C_{24}H_{36}O_2$

Relative Molecular mass

356.54

Structural formula



DHA EE

3. Physical and chemical properties

Appearance

Maxomega DHA 96 EE AS is a colourless-to-yellow, clear mobile liquid.

Solubility

Maxomega DHA 95 EE AS is practically insoluble in water, very soluble in organic solvents such as hexane, acetone, ethanol, and methanol.

Boiling point	> 400°C at 1.013hPa
Flash point	>100°C
Vapour pressure	Negliable
Density	0.914 g/cm^3 (20°C)
Partioning coefficient in octanol/water (logPow)	9.4

4. Medical information

Applications

Maxomega DHA 95 EE AS is a highly concentated omega-3 oil containing mainly only one of the omega-3 fatty acids, DHA in ethyl ester form. For application, Maxomega DHA 95 EE AS is typically filled into soft gelatin capsules as the sole fill ingredient. These soft gelatin capsules are suitable for Maxomega DHA EE AS because it protects the active substance from oxygen and masks taste and odour. In consequence, Maxomega DHA EE AS 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 DHA 95 EE AS is not used in any licenced pharmaceutical drug products, and there are no approved therapeutic indications for the generic substance Docosahexaenoic acid ethyl ester.

5. Handling & Safety

Please refer to the individual safety data sheet (SDS) for instructions on safe and proper handling and disposal. 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® (force.com).

Packaging

The commercial product is filled in epoxy phenolic lined mild steel drums. The lining is a golden brown colour. The drum closure is made of the same materials. The product is stored under nitrogen atmosphere to prevent oxidation. The external drum surface is blue.

6. Product specifications

The current version of the product specifications are available at RegXellence, RegXcellence® (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,, RegXcellence® (force.com)

PRD and Article numbers

PRD-No.*	Product name	Article numbers	Packaging
30635624	Maxomega DHA 95 EE AS	50461831	190kg steel drum
		50430534 (sample)	0,1 kg aluminum bottle

* BASF’s commercial product number.

June 2021