

Omega-3-Acid Ethyl Esters

(K85EE)

Highly concentrated and purified omega-3-acid ethyl esters used as an active ingredient in pharmaceutical drug products. Classified as a lipid-modifying agent.

BASF is a pioneer in the field of omega-3 oils

We offer a broad portfolio of **EPA** and **DHA** product combinations for the **pharmaceutical and dietary ingredient** industries.

Key customer benefits

- ✔ We supply our high-quality omega-3 products to customers all around the world
- ✔ The first EU-/ and FDA-approved omega-3-based prescription drug
- ✔ Our omega-3 supply chain team has a strong customer orientation, and a dedicated person will follow each delivery through the whole value-chain from release at our production site to the final destination
- ✔ Our omega-3 regulatory experts cover the whole value-chain, from source to finished product
- ✔ Our sustainable sourcing and production contribute to reduction of our customers carbon footprint
- ✔ Being a customer of BASF you can rely on a network of experts with knowledge of national regulations and the local language to optimally support your needs

Product details

| | | | |
|------------------------------|---|--|--|
| Chemical name | Omega-3-acid ethyl esters | | |
| Generic name | Omega-3-acid ethyl esters | | |
| CAS number | EPA EE 86227-47-6, DHA EE 81926-94-5 | | |
| Manufacturing site | BASF AS, Sandefjord, Norway | | |
| Manufacturing process | Semi-synthetic | | |
| Regulatory | ■ USP, Ph.Eur. ■ US-DMF, CEP, J-DMF, KR-DMF and CN-DMF available | | |
| | ■ GMP for APIs (ICH Q7 Guideline) ■ Complete pharma documentation available | | |
| Main application form | Soft gelatin capsules | | |
| PRD number | 30593627 for US, 30593631 for Japan only, 30593625 for Europe and countries accepting CEP, 30593633 for any territory except US and Japan, 30593626 for Italy only | | |
| Packaging and article number | 190 kg steel drums; 50355169 for US, 50355400 for Japan, 50355167 for Europe and those accepting CEP, 50355403 for any territory except US and Japan, 50355168 for Italy only | | |
| Sample and article number | 0.11 kg aluminum bottle; 50368780 for US, 50368784 for Japan only, 50368778 for Europe and countries accepting CEP, 50368786 for any territory except US and Japan, 50368779 for Italy only | | |
| Retest period | 24 months | | |
| Storage and transport | Store the substance under inert gas (nitrogen). Store the substance below 25 °C. Do not freeze. | | |

Inspiring Medicines for Better Lives
Contact us: omega3@basf.com

 BASF Pharma Solutions




We create chemistry





**BASF offers a
wide range of omega-3
products for use in
different applications**

| Omega-3 APIs/Ingredients | Description | Registration | Compendial compliance |
|-----------------------------------|--|---------------------------------------|-----------------------|
| Omega-3-Acid Ethyl Esters (K85EE) | Highly concentrated and purified EPA/DHA | US-DMF, CEP, J-DMF, KR-DMF and CN-DMF | USP, Ph.Eur. |
| Maxomega EPA 97 EE | Highly concentrated and purified EPA | J-DMF | JP |
| Maxomega EPA 96 EE | Highly concentrated and purified EPA | US-DMF, CN-DMF and IN-DMF | |
| Maxomega DHA 95 EE AS | DHA, algal-based | US-DMF in preparation | |
| CN 600 TG* | Omega-3-acid triglycerides | CEP and CN-DMF | Ph.Eur. |

* CN 600 TG = clinical nutrition, 600 mg/g triglycerides, Ingredient for the preparation of a Parenteral Nutrition Therapy

| Omega-3 Nutrition & Food | Description |
|--------------------------|---|
| PronovaPure® | Highly concentrated and purified marine omega-3 oil in different EPA/DHA combinations |
| Omega oils | Deodorized natural oils with excellent smell and taste profile |

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