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 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



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













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 in preparation	
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	
Dry n-3® omega-3 powders	Excellent flowability and high omega-3 pay-loads for use in infant nutrition and food applications	
Omega oils	Deodorized natural oils with excellent smell and taste profile	

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