

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	GSK2212836A EMULSION CAPSULE																
Synonym(s)	LOVAZA GELATIN CAPSULES * NDC NO. 0173-0783-01 * NDC NO. 0173-0783-02 * OMEGA-3-ACID ETHYL ESTERS, FORMULATED PRODUCT																
Recommended Use	Investigational Medicinal Product																
Company Name	<p>GlaxoSmithKline UK 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000</p> <p>GlaxoSmithKline US 5 Moore Drive Research Triangle Park, NC 27709 USA US General Information: +1-888-825-5249</p> <p>Email Address: msds@gsk.com Website: www.gsk.com</p> <p>EMERGENCY PHONE NUMBERS - Transport Emergencies (by country / geographic region):</p> <table style="width: 100%; border: none;"> <tr> <td style="padding-left: 20px;">Africa (Arab-speaking):</td> <td style="text-align: right;">+961-3-487-287 (Lebanon)</td> </tr> <tr> <td style="padding-left: 20px;">Africa (English, French, Portuguese-speaking):</td> <td style="text-align: right;">+44-208-762-8322 (UK)</td> </tr> <tr> <td style="padding-left: 20px;">Asia Pacific (except China):</td> <td style="text-align: right;">+65-633-44-177 (Singapore)</td> </tr> <tr> <td style="padding-left: 20px;">China:</td> <td style="text-align: right;">+86-10-5100-3039 (Beijing)</td> </tr> <tr> <td style="padding-left: 20px;">EU:</td> <td style="text-align: right;">+44-208-762-8322 (UK)</td> </tr> <tr> <td style="padding-left: 20px;">Israel:</td> <td style="text-align: right;">+44-208-762-8322 (UK)</td> </tr> <tr> <td style="padding-left: 20px;">Middle East (except Israel):</td> <td style="text-align: right;">+961-3-487-287 (Lebanon)</td> </tr> <tr> <td style="padding-left: 20px;">US:</td> <td style="text-align: right;">+1-703-527-3887 (US)</td> </tr> </table> <p>available 24 hrs/7 days; multi-language response</p> <p>Medical Emergencies: +1-612-221-3999, Ext 221 (US) available 24 hrs/7 days; multi-language response</p>	Africa (Arab-speaking):	+961-3-487-287 (Lebanon)	Africa (English, French, Portuguese-speaking):	+44-208-762-8322 (UK)	Asia Pacific (except China):	+65-633-44-177 (Singapore)	China:	+86-10-5100-3039 (Beijing)	EU:	+44-208-762-8322 (UK)	Israel:	+44-208-762-8322 (UK)	Middle East (except Israel):	+961-3-487-287 (Lebanon)	US:	+1-703-527-3887 (US)
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2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

Assume that this product is capable of sustaining combustion.

Health

Not expected to be a health hazard during normal handling. Health effects information is based on hazards of components.

Environment

No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
K-85EE OMEGA 3 CONCENTRATE	Unassigned	70	
Other components below reportable levels		30	

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	None.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

* 5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Fire and explosions might result if vapours are allowed to accumulate in the vicinity of a source of ignition.
Extinguishing Media	Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements Avoid breaking or crushing capsules.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT	K-85EE OMEGA 3 CONCENTRATE	
GSK Occupational Hazard Category	1	PROVISIONAL

Other Equipment or Procedures

None required for normal handling. Wash hands and arms thoroughly after handling.

* 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Gelatin capsule.

10. STABILITY AND REACTIVITY

Stability

This product is expected to be stable.

Conditions to Avoid

None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation

Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity

Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity

Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects

Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects

None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary

No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Not regulated in transport.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification Exempt when packaged for sale to consumers in a retail establishment.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 6

SDS Sections Updated**Sections**

FIRE FIGHTING MEASURES

PHYSICAL AND CHEMICAL PROPERTIES

Subsections

Extinguishing Media

Fire and Explosion Hazards

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.