

CERTIFICATE FOR SAFETY DATA SHEET

Name of the product: Omega-3-Acid ethyl esters capsules USP [1g] [Soft gelatin]

Product Code: 2002212

SDS Number: SDS/D1-001-01

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	RADHAKRISHNA DB	Rb 05/06/18
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Safety Data Sheet		
Company Name:	Strides Shasun Ltd	SDS Number: SDS/D1-001-01
Section 1: Identification		
Product Identifier		
Product name:	Omega-3-Acid ethyl esters capsules USP [1g] [Soft gelatin]	
Trade name:	Not applicable	
Product Code No.:	2002212	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	Medicinal Product (Lipid-regulating agent)	
Restrictions on Use:	No other uses are advised	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Shasun Limited	
Address:	Strides Shasun Limited No 36/7, Suragajakkannahalli, Indlavadi Cross, Anekal Taluk, Bengaluru, Karnataka, India. 562106	
Telephone Number- General:	91 8067 840307/309	
Emergency Telephone Number:	91 8067 840307/309	
Note: This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).		
Section 2: Hazard Identification:		
Hazard Classification of chemical mixture	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.	
Signal word	Not Available	
Hazard statement	Not Available	
Label elements		
Precautionary statements	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device	
Prevention	Not Available	
Response	Not Available	
Storage /Disposal EU classification US GHS Classification	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Dispose of contents/container in accordance with local/ regional/ national/ international Regulations.	
Hazard(s) not otherwise classified (HNOC)	Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.	
Section 3: Composition/Information on Ingredients		
Mixtures: Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and EU EINECS.		
Composition		

Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Omega -3- acid ethyl esters	EPA ethyl ester: 86227-47-6 DHA ethyl ester: 81926-94-5	*	Not Listed
Gelatin	9000-70-8	*	232-554-6
Glycerin	56-81-5	*	Not Listed
Purified water	7732-18-5	*	231-791-2
Opacode white ink (S-1-180000)	Not available	*	Not Listed
Isopropyl Alcohol	67-63-0	*	200-661-7
Medium chain Triglyceride	73398-61-5	*	Not Listed

* Percentage composition is not captured due to trade secret.

Section 4: First aid measures

General Information: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Inhalation:	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin:	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye:	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Ingestion:	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms and effects both acute and delayed:

Symptoms	Not applicable
Other hazards	Not applicable

UN GHS/ EU EINECS

Effects	Not applicable
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Indication of immediate medical attention and special treatment needed

Notes for the doctor	No specific antidotes are recommended. Treat according to locally accepted protocols.
Special treatment	For additional guidance, refer to the current prescribing information or to the local poison control information center.
Other information	Not applicable

Section 5: Fire Fighting Measures

Extinguishing media

Suitable Extinguishing Media	Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable Extinguishing Media	Do NOT use water.

Firefighting Procedures	Move containers from fire area if you can do so without risk.. In the event of fire and/or explosion do not breathe fumes.
Un usual fire and Explosion Hazards	Not applicable
Hazardous combustion products	During fire, gases hazardous to health may be formed.
Additional Information	
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	This product will support combustion at elevated temperature.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions:	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
Emergency procedures:	No data available
Methods and material for containment and cleaning up	
Containment/Cleanup measures	Large Spills: Stop the flow of material, if this is without risk. Following product recovery, flush area with water.
Prohibited materials	Not applicable

Section 7: Handling and Storage

Precautions for safe handling

Protective measures:

Safe handling	No special control measures required for the normal handling of this product.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
Fire Prevention	Not applicable
Dust generation Preventions	Not applicable
Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
Special Packaging Materials	Not applicable
Requirement for storage rooms and assembly:	Not applicable
Incompatible materials or ignition sources:	incompatible materials (see Section 10 of the SDS).

Section 8: Exposure Controls and personal protection

Control parameters:

Exposure Limits/Guidelines: Refer the occupational exposure limits / guidelines for the individual product components

Component Name	Result	OSHA	Other agency Information
Omega -3- acid ethyl esters	OHC	1	No data available
Gelatin	TWA	No data available	No data available
Glycerin	TWA	No data available	No data available

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Purified Water	TWA	No data available	No data available
Opacode white ink (S-1-180000)	TWA	No data available	No data available
Isopropyl Alcohol	TWA	400 ppm	200 ppm, 400 ppm
Medium chain Triglyceride	PEL/TWA	No data available	No data available
Biological limit values: No biological exposure limits noted for the ingredient(s).			
Control Parameters			
Exposure Limits/ Guidelines: Refer to the occupational exposure limits / guidelines for the individual product components.			
Engineering Controls	General ventilation normally adequate. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.		
Individual protection measures, such as personal protective equipment			
Hands:	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.		
Eyes	Not normally needed. If contact is likely, safety glasses with side shields are recommended.		
Skin	Not required for the normal use of this product. For prolonged or repeated skin contact use suitable protective clothing.		
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.		
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.		
Special requirements for PPE	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.		
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.		

Section 9: Physical and Chemical properties

Information on physical and chemical Properties

Material Description:	Clear, natural colored oblong shaped soft gelatin capsules containing pale yellow colored oily liquid imprinted with '740'		
Physical Form:	Solid		
Color:	Pale yellow colored		
Odour:	Not Available		
General Properties:	Boiling point	Not available	Melting point
Water solubility:	Water miscible	Solvent solubility:	Not available
Specific gravity / Relative density	Not available	pH	Not available
Decomposition temperature	Not available	Viscosity	Not available

Density	Not available	Partition coefficient	Not available
Volatility & Flammability:			
Vapor pressure	Not relevant	Vapor density	Not relevant
Evaporation rate	Not available	UEL (Upper Exposure limit)	Not available
Flash Point	Not available	LEL (Lower Exposure limit)	Not available
Flammability (solid, gas)	Not available		

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Any stabilizer requirement on storage	Not required
Conditions to avoid	Keep away from heat, open flames and sparks. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

Section 11: Toxicological information

Information on toxicological effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Components	CAS No	Acute toxicity
Omega -3- acid ethyl esters	EPA ethyl ester: 86227-47-6 DHA ethyl ester: 81926-94-5	LD50 Oral - mouse >20g/kg Rat >20g/kg
Gelatin	9000-70-8	LD50 Oral Rat >3750 mg/kg LD50 Dermal Rabbit > 3600mg/kg
Glycerin	56-81-5	LD50 Oral - rat - 12600 mg/kg LD50 Dermal-rabbit >10000mg/kg
Purified water	7732-18-5	Not available
Opacode white ink (S-1-180000)	Not available	Not available
Isopropyl Alcohol	67-63-0	LD50 Oral Mouse > 3600mg/kg
Medium chain Triglyceride	73398-61-5	LD60 Oral Rat > 5000mg/kg

Potential Health Effects

Inhalation

Acute (immediate) Not relevant

Chronic (delayed) Not relevant

Skin

Acute (immediate) Not relevant

Chronic (delayed)	Not relevant
Eye	
Acute (immediate)	May cause temporary eye irritation.
Chronic (delayed)	May cause eye irritation.
Ingestion	
Acute (immediate)	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard.
Chronic (delayed)	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard.

Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
Skin corrosion/irritation:	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Respiratory sensitization	No studies have been conducted.
Skin sensitization	None known. This product is not expected to cause skin sensitization.
Germ cell mutagenicity:	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity:	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.
Reproductive toxicity:	Contains no ingredient listed as toxic to reproduction
Further information:	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.

Section 12: Ecological Information

Ecotoxicity	Not expected to be harmful to aquatic organisms
Persistence and degradability	Not Available
Bio accumulative potential	Not Available
Mobility in Soil	Not Available
Mobility in general	Not Available
Other adverse effects	Not Available

Section 13: Disposal Considerations

Product waste	<p>Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.</p> <p>Local disposal regulations: Dispose in accordance with all applicable regulations.</p> <p>Hazardous waste code: the waste code should be assigned in discussion between the user, the producer and the waste disposal company.</p>
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	Waste from residues / unused products: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Packaging waste	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14: Transport information

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN Number	Not applicable
UN shipper name	Not applicable
Transport hazard class	Not Dangerous goods
Environmental hazards	Not dangerous goods
DOT	Not regulated as a dangerous good.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not Applicable

Section 15: Regulatory Information

Safety, Health and environmental regulations/legislation specific for the substance or Mixture

Components	CAS No	CERCLA/SARA Emission Reporting
Omega -3- acid ethyl esters	EPA ethyl ester: 86227-47-6 DHA ethyl ester: 81926-94-5	Not Listed
Gelatin	9000-70-8	Not Listed
Glycerin	56-81-5	Not Listed
Purified water	7732-18-5	Not Listed
Opacode white ink (S-1-180000)	Not available	Not Listed
Isopropyl Alcohol	67-63-0	Not Listed
Medium chain Triglyceride	73398-61-5	Not Listed

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D):	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4):	Not listed.
SARA 304 Emergency release notification:	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):	Not listed.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List	Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):	Not regulated.
Safe Drinking Water Act (SDWA):	Not regulated.
US state regulations	
US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100):	Not listed.
US. Massachusetts RTK - Substance List:	Not regulated.
US. New Jersey Worker and Community Right-to-Know Act:	Not listed.
US. Pennsylvania Worker and Community Right-to-Know Law:	Not listed.
US. Rhode Island RTK:	Not regulated.
US. California Proposition 65	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

Section 16: Other information

Disclaimer: 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 purpose.

Reason for revision: (Include Change control number)	New Safety data sheet prepared
Revision date:	05/06/2018
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