

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** **Omegaven (fish oil triglycerides) Injectable Emulsion**  
**Synonyms:** Omegaven 10%, Emulsion for Infusion  
**Manufacturer Name:** Fresenius Kabi Austria GmbH  
**Address:** Hafnerstrasse 36  
 Graz , 8055  
 Austria  
**General Phone Number:** +43.316.249.0  
**Distributor Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
 Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** July 18, 2018

### SECTION 2 : HAZARD(S) IDENTIFICATION

**Signal Word:** Not applicable.  
**Hazard Statements:** Not applicable.  
**Precautionary Statements:** Not applicable.  
**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Avoid contact with skin, eyes, nostrils and mouth.  
**Route of Exposure:** Inhalation Ingestion Eye contact Skin Absorption. Injection.  
**Eye:** Contact with eyes may cause irritation.  
**Skin:** May cause skin irritation.  
**Inhalation:** not hazardous by inhalation.  
**Ingestion:** Ingestion of the product may produce gastrointestinal irritation and disturbances.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Water	7732-18-5	Remainder by weight	
Nitrogen	7727-37-9	Q.S. by weight	
Glycerol	56-81-5	25 g/1000mL by weight	
D,L- $\alpha$ -tocopherol	7695-91-2	150 - 296 mg/1000mL by weight	
Sodium oleate	143-19-1	300 mg/1000mL by weight	
Purified Egg Phospholipid	93685-90-6	12 g/1000mL by weight	
Sodium hydroxide	1310-73-2	20 mg/1000mL by weight	
Triglycerides	8016-13-5	100 g/1000mL by weight	

### SECTION 4 : FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.  
**Skin Contact:** Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.  
**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.  
**Ingestion:** If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give

anything by mouth to an unconscious person.

**Other First Aid:** For Adverse Event Information, please call Vigilance: (905) 770-3711.

## SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	Evacuate area of unprotected personnel. Exercise caution when fighting any chemical fire. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
<b>Extinguishing Media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable Media:</b>	Do not use a solid water stream as it may scatter and spread fire.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	Carbon oxides. Sodium oxides. Chlorine.
<b>Universal Fire And Explosion Hazards:</b>	Not considered flammable but may burn at high temperatures.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

## SECTION 7 : HANDLING and STORAGE

<b>Handling:</b>	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
<b>Storage:</b>	Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Store away from incompatible materials.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
<b>Eye/Face Protection:</b>	Chemical goggles.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site ( <a href="http://www.cdc.gov/niosh/nppt/topics/respirators/">http://www.cdc.gov/niosh/nppt/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

### EXPOSURE GUIDELINES

#### **Glycerol:**

**Guideline ACGIH:** TLV - STEL: 10 mg/m<sup>3</sup>

**Guideline OSHA:** PEL - STEL: 5mg/m<sup>3</sup>

#### **Triglycerides:**

**Guideline ACGIH:** TLV-STEL: 2 ppm (ceiling)

**Guideline OSHA:** OSHA PEL-STEL 5 ppm Ceiling/Peak

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Clear
Odor:	Not available.
Odor Threshold:	Not available.
Boiling Point:	Not available.
Melting Point:	Not established.
Density:	Not available.
Specific Gravity:	Not available.
Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not available.
Percent Volatile:	Not established.
Evaporation Rate:	Not available.
pH:	Not available.
Viscosity:	Not available.
Flammability:	Not available.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

## SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Reactivity:	Hazardous reactions will not occur under normal conditions.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Direct sunlight. Extremely high or low temperatures.
Incompatible Materials:	Incompatible with strong acids and bases. Strong oxidizing agents.
Special Decomposition Products:	Carbon oxides (CO, CO <sub>2</sub> ). Sodium oxides. Chlorine.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### Glycerol :

Ingestion: Oral - Rat LD50: 25,800 mg/kg

### D,L- $\alpha$ -tocopherol :

Skin: Dermal - Rat LD50: >7940 mg/kg

Ingestion: Oral - Rat LD50: 8290 mg/kg

### Sodium oleate :

Ingestion: Oral - Rat LD50: 17 g/kg

### Sodium hydroxide :

RTECS Number: WB4900000

Ingestion: Oral - Rat LD50: 2,600 mg/kg

### Triglycerides :

Eye: Eye - Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)

Skin: Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)

Inhalation: Inhalation - Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis]  
Inhalation - Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)]  
Inhalation - Rat LC50: 45000 mg/m<sup>3</sup>/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - Rat LC50: 8300 mg/m<sup>3</sup>/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - Mouse LC50: 8300 mg/m<sup>3</sup>/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - LC50: 0.1 gm/m<sup>3</sup> [Details of toxic effects not reported other than lethal dose value]  
Inhalation - Rat LC50: 60938 mg/m<sup>3</sup>/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - Mouse LC50: 20487 mg/m<sup>3</sup>/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - Rat LC50: 7004 mg/m<sup>3</sup>/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - Mouse LC50: 3940 mg/m<sup>3</sup>/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]  
Inhalation - Rat LC50: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value]  
Inhalation - Mouse LC50: 2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)

Ingestion: Oral - Rabbit LD50: 900 mg/kg [Details of toxic effects not reported other than lethal dose value]

**SECTION 12 : ECOLOGICAL INFORMATION**

<b>Ecotoxicity:</b>	No ecotoxicity data was found for the product.
<b>Environmental Stability:</b>	No environmental information found for this product.
<b>Bioaccumulation:</b>	No information.
<b><u>Glycerol :</u></b>	
<b>Ecotoxicity:</b>	LC50 fishes 1 51 (51 - 57) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) EC50 Daphnia 1 > 500 mg/l (Exposure time: 24 h - Species: Daphnia magna)
<b><u>Sodium hydroxide :</u></b>	
<b>Ecotoxicity:</b>	LC50 fishes 1 1060 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) EC50 Daphnia 1 825 mg/l (Exposure time: 48 h - Species: Daphnia magna) EC50 other aquatic organisms 1 2500 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus) LC50 fish 2 750 - 1020 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) EC50 Daphnia 2 83 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
<b>Notes :</b>	Avoid release to the environment.

**SECTION 13 : DISPOSAL CONSIDERATIONS**

<b>Waste Disposal:</b>	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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**SECTION 14 : TRANSPORT INFORMATION**

<b>DOT Shipping Name:</b>	Not Regulated.
<b>DOT UN Number:</b>	Not Regulated.

**SECTION 15 : REGULATORY INFORMATION**

<b><u>Glycerol :</u></b>	
<b>TSCA Inventory Status:</b>	Listed
<b>EINECS Inventory Status:</b>	Listed
<b>Canada DSL:</b>	Listed
<b><u>D,L-<math>\alpha</math>-tocopherol :</u></b>	
<b>TSCA Inventory Status:</b>	Listed
<b>EINECS Inventory Status:</b>	Listed
<b>Canada DSL:</b>	Listed
<b><u>Sodium oleate :</u></b>	
<b>TSCA Inventory Status:</b>	Listed
<b>EINECS Inventory Status:</b>	Listed
<b>Canada DSL:</b>	Listed
<b><u>Sodium hydroxide :</u></b>	
<b>TSCA Inventory Status:</b>	Listed
<b>EINECS Inventory Status:</b>	Listed
<b>Canada DSL:</b>	Listed
<b>Canada WHMIS:</b>	Class D Division 2 Subdivision B - Toxic material causing other toxic effects
<b><u>Triglycerides :</u></b>	
<b>TSCA Inventory Status:</b>	Listed
<b>SARA:</b>	EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
<b>Section 302 EHS:</b>	EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500 Lbs.
<b>Section 304 RQ:</b>	EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 5,000 Lbs.
<b>Canada DSL:</b>	Listed
<b>Canada IDL:</b>	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

**SECTION 16 : ADDITIONAL INFORMATION****HMIS Ratings:**

HMIS Health Hazard: 1  
HMIS Fire Hazard: 0  
HMIS Reactivity: 0  
HMIS Personal Protection: X

SDS Creation Date:

July 18, 2018

Disclaimer:

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