SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Smoflipid 20%, emulsion for infusion**
Manufacturer Name:	Fresenius Kabi AB (Sweden)
Address:	SE 751 74 Uppsala, Sweden
General Phone Number:	+46 (0)18-64 40 00
General Fax Number:	+46 (0)18-64 49 20
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:	December 21, 2015
SDS Revision Date:	December 21, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

Signal Word:	Not applicable.
GHS Class:	Not classified as hazardous according to OSHA Hazard Communication Standard, 29 CFR 1910.1200.. .
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.
Route of Exposure:	Inhalation Ingestion Eye contact Skin Absorption. Injection.
Potential Health Effects:	
Eye:	Contact with eyes may cause irritation.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Medium chain triglycerides	65381-09-1	60 mg/mL	265-724-3
Soybean Oil	8001-22-7	60 mg/mL	232-274-4
Olive oil	112-80-1	50 mg/mL	204-007-1
Fish oil, rich in omega-3 acids	8002-50-4	30 mg/mL	232-311-4
Glycerol	56-81-5	25 mg/mL	200-289-5
Egg phospholipid	93685-90-6	12 mg/mL	297-639-2
Vitamin E	59-02-9	0.163 - 0.225 mg/mL	200-412-2
Sodium hydroxide	1310-73-2	As needed to adjust pH 8	215-185-5
Water for injection	7732-18-5	to 1000 ml	231-791-2

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 (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	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.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	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

Handling:	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.
Storage:	Store at 20° to 25°C (68°to 77°F) [See USP Controlled Room Temperature]. Do not freeze.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	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.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	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 (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Glycerol :

Guideline ACGIH:	TLV-TWA: 10 mg/m3
Guideline OSHA:	PEL-TWA: 15 mg/m3 Total particulate/dust (T)

	PEL-TWA: 5 mg/m3 Respirable fraction (R)
Sodium hydroxide :	
Guideline ACGIH:	TLV-STEL: C 2 mg/m3
Guideline OSHA:	PEL-TWA: 2 mg/m3

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Milky white.
Odor:	Not determined.
Odor Threshold:	Not determined.
Boiling Point:	Not determined.
Melting Point:	Not determined.
Density:	Not determined.
Solubility:	Soluble in water.
Vapor Density:	Not determined.
Vapor Pressure:	Not determined.
Percent Volatile:	Not determined.
Evaporation Rate:	Not determined.
pH:	6.0 - 9.0
Viscosity:	Not determined.
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.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Teratogenicity:	Pregnancy Category B: No adequate and well-controlled studies in pregnant women are available. However, reproductive studies have been performed in rats and rabbits at intravenous doses of 15 mg/kg and have revealed no evidence of impaired fertility or harm to the fetus due to propofol.
Soybean Oil :	
RTECS Number:	WG4862000
Other Toxicological Information:	Intravenous. - Rat LD50: 16500 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 22100 mg/kg [Details of toxic effects not reported other than lethal dose value]
Glycerol :	
RTECS Number:	MA8050000
Eye:	Administration into the eye - Rabbit Standard Draize test: 500 mg/24H [Mild] (RTECS)
Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H
Inhalation:	Inhalation - Rat LC50: >570 mg/m3/1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 12600 mg/kg [Behavioral - General anesthetic Behavioral - Muscle weakness Liver - Other changes] Oral - Rat LD50 - Lethal dose, 50 percent kill: 12600 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intravenous. - Rat LD50: 5566 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 4250 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LD50: 53 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: 100 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 91 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 4420 mg/kg [Behavioral - toxic psychosis Cardiac - other changes Kidney/Ureter/Bladder - other changes] Intraperitoneal. - Mouse LD50: 8700 mg/kg [Behavioral - altered sleep time (including change in righting reflex)]
Sodium hydroxide :	

Eye:	Administration into the eye - Rabbit Standard Draize test: 400 ug [Mild] Administration into the eye - Rabbit Standard Draize test: 1 % [Severe] Administration into the eye - Rabbit Standard Draize test: 50 ug/24H [Severe] Administration into the eye - Rabbit Standard Draize test: 1 mg/24H [Severe] Administration into the eye - Rabbit Rinsed with water: 1 mg/30S [Severe] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Medium chain triglycerides :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	265-724-3

Soybean Oil :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	232-274-4

Olive oil :

EC Number:	204-007-1

Fish oil, rich in omega-3 acids :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	232-311-4

Glycerol :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	200-289-5

Egg phospholipid :

Canada DSL:	Listed
EC Number:	297-639-2

Vitamin E :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	200-412-2

Sodium hydroxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	215-185-5

Water for injection :

EC Number:	231-791-2

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1

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

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Disclaimer:

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