

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:

Kabiven

Product Use/Restriction:

For intravenous infusion into a central vein as a source of calories, protein and essential fatty acids for patients requiring parenteral nutrition in four sizes 1026 ml, 1540 ml, 2053 ml, and 2566 ml.

This product is supplied in a three chamber bag: Chamber 1 contains Dextrose solution for fluid replenishment and caloric supply.

The Amino Acid solution with Electrolytes, in chamber 2 comprises essential and nonessential amino acids provided with electrolytes.

Chamber 3 contains Intralipid® 20% (a 20% Intravenous Fat Emulsion), prepared for intravenous administration as a source of calories and essential fatty acids.

Manufacturer Name:

Fresenius Kabi AB (Sweden)

Address:

SE 751 74 Uppsala, Sweden +46 (0)18-64 40 00 +46 (0)18-64 49 20

General Phone Number: General Fax Number: Distributor Name: Address:

Fresenius Kabi USA, LLC Three Corporate Drive Lake Zurich, Illinois 60047

General Phone Number: Customer Service Phone (847) 550-2300 (888) 386-1300

Number:

Health Issues Information: (800) 551-7176



SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Water for Injection	7732-18-5	quantity sufficient	
L-Alanine	56-41-7	4.7 grams/1000 mL	
L-Arginine	74-79-3	3.3 grams/1000 mL	
L-Aspartic acid	56-84-8	0.99 grams/1000 mL	
L-Glutamic acid	617-65-2	1.6 grams/1000 mL	
Glycine (Aminoacetic acid)	56-40-6	2.3 grams/1000 mL	
L-Histidine	71-00-1	2 grams/1000 mL	
L-Isoleucine	73-32-5	1.6 grams/1000 mL	
L-Leucine	61-90-5	2.3 grams/1000 mL	
L-Lysine	56-87-1	2.6 grams/1000 mL	
L-Methionine	63-68-3	1.6 grams/1000 mL	
L-Phenylalanine	63-91-2	2.3 grams/1000 mL	
L-Proline	147-85-3	2 grams/1000 mL	
L-Serine	56-45-1	1.3 grams/1000 mL	
L-Threonine	72-19-5	1.6 grams/1000 mL	
L-Tryptophan	73-22-3	0.55 grams/1000 mL	
L-Tyrosine	60-18-4	0.07 grams/1000 mL	
L-Valine	72-18-4	2.1 grams/1000 mL	
Calcium chloride	10043-52-4	0.22 grams/1000 mL	
Sodium glycerophosphate (anhydrous)	1334-74-3	1.5 grams/1000 mL	
Magnesium sulphate	10034-99-8	0.47 grams/1000 mL	
Potassium chloride	7447-40-7	1.7 grams/1000 mL	
Sodium acetate	127 09 3	1.4 grams/1000 mL	
Glucose	50-99-7	97 grams/1000 mL	

Soybean oil 8001-22-7 39 grams/1000 mL

Soybean Oil USP 3.9 grams/100 ml N/A

Amino acids, USP N/A 3.31 grams/100 ml

50-99-7 9.8 grams/100 ml Dextrose

SECTION 3: HAZARDS IDENTIFICATION

Emergency Overview: Non hazardous.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects: No effects expected. Signs/Symptoms: No effects expected. Aggravation of Pre-Existing No effects expected.

Conditions

SECTION 4: FIRST AID MEASURES

Eye Contact: No unusual emergency conditions are expected from this product. Skin Contact: No unusual emergency conditions are expected from this product. Inhalation: No unusual emergency conditions are expected from this product. Ingestion: No unusual emergency conditions are expected from this product.

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: Not applicable. Extinguishing Media: Not applicable. Protective Equipment: Not applicable. Hazardous Combustion Not applicable. Byproducts:

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions: Not applicable. **Environmental Precautions:** Not applicable.

Methods for containment: Contain spill using inert absorbent material.

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. Methods for cleanup:

SECTION 7: HANDLING and STORAGE

Handling: Not applicable.

Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Do not freeze. Storage:

Work Practices: Not applicable. Hygiene Practices: Not applicable.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION - EXPOSURE GUIDELINES

Not applicable. (General ventilation is sufficient if this product is being used in a controlled art studio **Engineering Controls:**

setting for its sole intended photo-shooting purpose for the Marketing Catalog. NOTE: This product demo is a dummy for product catalog photo-shooting only; thus it is not a real pharmaceutical

injectable product. It is not intended for real parenteral (injection) purposes).

Eye/Face Protection: Not applicable. Skin Protection Description: Not applicable

Hand Protection Description: Not applicable.

Respiratory Protection: Not applicable.

EXPOSURE GUIDELINES

SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

Physical State: Liquid.
Color: Clear

Boiling Point: Not established.

Melting Point: Not established.

Solubility: Soluble. in water.

Vapor Density: Not established.

Vapor Pressure: Not established.

Percent Volatile: Not established.

pH: 5.6

Molecular Formula: Mixture

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: Protect from freezing.

SECTION 11: TOXICOLOGICAL INFORMATION

Eye: Non hazardous.

Skin: Non hazardous.

Inhalation: Non hazardous.

Ingestion: Non hazardous.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: This material is not expected to cause harm to animals, plants or fish.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: This material is not expected to be a characteristic hazardous waste under RCRA.

SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15: REGULATORY INFORMATION

TSCA Inventory Status: Not Regulated.

Canada DSL: Not Regulated.

SECTION 16: ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 0
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: A

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