

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: Caspofungin Acetate for Injection 50mg and 70mg

Other means of identification:

Recommended use of the chemical and restrictions on use:

Product Use/Restriction: Anti-fungal

Chemical manufacturer address and telephone number:

Manufacturer 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

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Pictograms:



Signal Word: DANGER!

GHS Class: Reproductive Toxicity, Category 2
 Eye Damage, Category 1
 Hazardous to the aquatic environment, Acute, Category 1

Hazard Statements: H318: Causes serious eye damage.
 H361: Suspected of damaging fertility or the unborn child.
 H400: Very toxic to aquatic life.

Precautionary Statements: P310: Immediately call a POISON CENTER or doctor/physician.
 P391: Collect spillage.
 P201: Obtain special instructions before use.
 P280: Wear protective gloves/protective clothing/eye protection/face protection.
 P202: Do not handle until all safety precautions have been read and understood.
 P281: Use personal protective equipment as required.
 P260: Avoid breathing dust/fume/gas/mist/vapours/spray.
 P264: Wash hands thoroughly after handling.
 P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P273: Avoid release to the environment.

Hazards not otherwise classified that have been identified during the classification process:

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: Severe eye irritation.
Skin: May cause skin irritation.
Inhalation: May cause irritation of respiratory tract.
Ingestion: This route of entry is unlikely. If ingested, substance is considered non-toxic.

Caspofungin acetate

Signs/Symptoms: The most common adverse effects reported in patients were fever, headache, infused vein complications, nausea, vomiting, flushing and chills. In humans, possible histamine-mediated symptoms have been reported including rash, facial swelling, itching, sensation of warmth, or bronchospasm. Anaphylaxis has been reported. These effects have been reported in individuals receiving the drug intravenously and their relevance to workplace exposures is unknown. Liver function test abnormalities have occurred in healthy volunteers and patients receiving candidas. Repeat-dose intravenous (IV) studies in animals resulted in systemic reactions attributed to histamine release and liver toxicity in the rat and monkey. Fertility and reproductive performance were not affected by the intravenous administration of caspofungin to rats. It was shown to cause adverse developmental

effects in rats and rabbits and was found in the milk of lactating, drug-treated rats.

Aggravation of Pre-Existing Conditions:

Individuals with moderate liver insufficiency will be more sensitive.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Arginine	74-79-3	64.7% (100 mg/ 140 mg) by weight	
Caspofungin acetate	179463-17-3	35.3 % (54.6 mg/ 77.2 mg) by weight	
Sodium hydroxide	1310-73-2	As needed to adjust pH	
Hydrochloric acid	7647-01-0	As needed to adjust pH	

SECTION 4 : FIRST AID MEASURES

Description of necessary 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.

Most important symptoms/effects, acute and delayed:

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable 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.

Specific hazards arising from the chemical:

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.

Special protective equipment and precautions for fire-fighters:

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

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.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.

Environmental precautions:

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up:

Methods for containment: This material will settle out of the air.
Methods for cleanup: Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

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.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

Conditions for safe storage, including any incompatibilities:

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Lyophilized powder.

Specific end use(s):

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Caspofungin acetate :

Guideline Type: OEL
Guideline Info: 0.075 mg/m³ (TWA)

Hydrochloric acid :

Guideline ACGIH: TLV-STEL: 2 ppm (ceiling)
Guideline OSHA: OSHA PEL-STEL 5 ppm Ceiling/Peak

Appropriate engineering controls:

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.

Individual protection measures:

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.

General Hygiene Considerations: Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Lyophilized powder.
Color: White to slightly yellow
The reconstituted liquid is colorless to light yellow
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: 6.5 - 7.5 after reconstitution
Molecular Formula: Mixture
Molecular Weight: 1750
Flash Point: Not established.
Flash Point Method: Not established.

Lower Flammable/Explosive Limit: Not established.
Upper Flammable/Explosive Limit: Not established.
Auto Ignition Temperature: Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability: Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization: Not reported.

Conditions To Avoid:

Conditions to Avoid: Avoid direct sunlight, conditions that might generate heat, and sources of ignition. Avoid contact with incompatible materials.

Incompatible Materials:

Incompatible Materials: Avoid storage near oxidizers.

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Teratogenicity: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Since colistimethate sodium is transferred across the placental barrier in humans, it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Caspofungin acetate :

Ingestion: Oral - Rat LD50 : 5450 mg/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Lungs, Thorax, or Respiration - Other changes]
Oral - Mouse LD50 : >767 mg(base)/kg [Details of toxic effects not reported other than lethal dose value]

Sodium hydroxide :

RTECS Number: WB4900000

Ingestion: Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

Hydrochloric acid :

RTECS Number: MW4025000

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/m³/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50: 8300 mg/m³/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 8300 mg/m³/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - LC50: 0.1 gm/m³ [Details of toxic effects not reported other than lethal dose value]
Inhalation - Rat LC50: 60938 mg/m³/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 20487 mg/m³/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50: 7004 mg/m³/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 3940 mg/m³/30M [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] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity: Very toxic to aquatic organisms.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

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.

IATA Shipping Name: Environmentally hazardous substance, solid n. o. s.
 IATA UN Number: 3077
 IATA Hazard Class: 9
 IATA Packing Group: III

IMDG UN Number : 3077
 IMDG Shipping Name : Environmentally hazardous substance, solid n.o.s.
 IMDG Hazard Class : 9
 IMDG Packing Group : III
 EMS No. F-A, S-F

Marine Pollutant: Marine pollutant

SECTION 15 : REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product:

Caspofungin acetate :

TSCA Inventory Status: Listed
 Canada DSL: Listed

Sodium hydroxide :

TSCA Inventory Status: Listed
 Canada DSL: Listed

Hydrochloric acid :

TSCA Inventory Status: Listed
 EINECS Number: 231-595-7
 Canada DSL: Listed
 Canada IDL: 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: 1
 HMIS Reactivity: 0
 HMIS Personal Protection: X

Health Hazard	1
Fire Hazard	1
Reactivity	0
Personal Protection	X

SDS Creation Date: September 17, 2012
 SDS Revision Date: July 27, 2017

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