

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Cefepime For Injection, USP
Manufacturer Name: ABL - Antibióticos Do Brasil, Ltda.
Address: Rod. General Milton Tavares de Souza
 SP (332), km 135
 Bairro Itavapavussu, Cosmópolis São Paulo, Brasil
General Phone Number: 55 19 3872-9300
Customer Service Phone Number: 55 19 3872-9300
Emergency Phone Number: InterChem - 201-261-7333 Mike Queirolo
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: September 01, 2017
SDS Revision Date: July 19, 2018

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER!

GHS Class: Skin Sensitizer, Category 1A. Eye Damage, Category 1. Respiratory Sensitizer, Category 1.

Hazard Statements: May cause an allergic skin reaction. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements: Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. In case of inadequate ventilation wear respiratory protection. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Avoid breathing dust/fume/gas/mist/vapours/spray. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

L-Arginine

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: Can cause severe eye injury.

Skin: May cause skin sensitization, an allergic reaction, which becomes evident on reexposure to this material.

Inhalation: May cause respiratory sensitization with asthma-like symptoms in susceptible individuals.

Signs/Symptoms: Possible adverse reactions include: local reactions, rash, diarrhea, nausea, vomiting, pruritus, positive Coombs' test, and other laboratory changes. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a known hypersensitivity to cefepime or the cephalosporin class of antibiotics, penicillins, or other beta-lactam antibiotics. Kidney disease may be aggravated by some cephalosporins.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
L-Arginine	74-79-3	30 - 40% by weight (707mg/g)	

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 dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
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

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 in the dry state @ 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light. Retain in carton until time of use.
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 dust, 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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Crystalline powder.
Color:	White to pale yellow.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Freely soluble
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.0 - 6.0
Molecular Formula:	Mixture
Molecular Weight:	477.46
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

L-Arginine :

Reproductive Toxicity:	Pregnancy Category B: There are no adequate and well-controlled studies of cefepime use in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
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SECTION 12 : ECOLOGICAL INFORMATION

L-Arginine :

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

SECTION 13 : DISPOSAL CONSIDERATIONS

L-Arginine :

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

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

SECTION 15 : REGULATORY INFORMATION

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Personal Protection: 1

SDS Creation Date: September 01, 2017

SDS Revision Date: July 19, 2018

SDS Revision Notes: "Update Manufacturer Info"

Disclaimer:

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