

## Safety Data Sheet

### Section 1. Identification

**Common/Trade name** : Cefepime for Injection; Cefepime for Injection, USP

**Recommended use** : Pharmaceutical industry: Dosage form  
Therapeutic category: Antibiotic

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

**Recommended restrictions** : No other uses are advised.

<p><b>Supplier</b> : <b>Canada</b></p> <p>Apotex Inc. 150 Signet Drive Toronto, Ontario M9L 1T9 416-749-9300</p>	<p><b>U.S.</b></p> <p>Apotex Corp. 2400 N. Commerce Parkway Suite 400 Weston, FLA 33326 Telephone: (954)384-8007 Toll Free: 1-800-706-5575</p>
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**Emergency phone** : United States/Canada (Chemtrec) 1-800-424-9300 or  
+1 703-527-3887 (24 hours)  
For general information call:  
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

### Section 2. Hazards Identification

**Classification of the substance or mixture** : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

**GHS label elements** : Exempt from requirements.

**Hazards not otherwise classified** : Exempt from requirements.

### Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Cefepime hydrochloride Arginine	123171-59-5	60-100 to adjust pH
Specific chemical identity and/or percentage of composition has been withheld as a trade secret.		

**Chemical name** : 1-[[[(6R, 7R)-7-[2-(2-amino-4-thiazolyl)-glyoxylamido]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methylpyrrolidinium chloride, 72\_-(Z)-(O-methyloxime), monohydrochloride, monohydrate  
Cefepime is buffered with L-Arginine to adjust the pH between 4- 6 for the final product.

**Synonyms** : Not available.

**Chemical family** : Cephalosporin.

**Molecular weight** : Not applicable.

**Chemical formula** : C<sub>19</sub>H<sub>25</sub>ClN<sub>6</sub>O<sub>5</sub>S<sub>2</sub> . HCl . H<sub>2</sub>O

## Section 4. First Aid Measures

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : Flush with copious amounts of water. Seek medical attention if irritation persist.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

## Section 5. Fire Fighting Measures

- Specific hazard arising from the chemical** : During fire, gases hazardous to health may be formed.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## Section 6. Accidental Release Measures

- Methods and materials for containment and cleaning up** : Assess hazard levels. Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment.

## Section 7. Handling and Storage

- Precautions for safe handling** : Avoid breathing dust.
- Conditions for safe storage** : Store as directed by product packaging.

## Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

<b>Personal Protection</b>	: Skin: Lab coat
	Respiratory: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, an approved NIOSH respirator may be required.
	Hand: Nitrile gloves
	Eye: Safety glasses
<b>Occupational exposure limits</b>	: Not established.

## Section 9. Physical and Chemical Properties

<b>Physical state and appearance</b>	: White to almost white powder.		
<b>pH</b>	: Not available.	<b>Odor</b>	: Not available.
<b>Melting point/Freezing point</b>	: Not available.	<b>Odor threshold</b>	: Not available.
<b>Boiling point</b>	: Not available.	<b>Conditions of instability</b>	: Not available.
<b>Volatility</b>	: Not available.	<b>Decomposition temperature</b>	: Not available.
<b>Specific gravity</b>	: Not available.	<b>Partition Coefficient:</b>	: Not available.
<b>Evaporation rate</b>	: Not available.	<b>Viscosity</b>	: Not available.
<b>Vapor density</b>	: Not available.	<b>Flash points</b>	: Not available.
<b>Relative density</b>	: Not available.	<b>Flammable limits</b>	: Not available.
<b>Vapor pressure</b>	: Not available.	<b>Autoignition temperature</b>	: Not available.
<b>Flammability</b>	: Emits toxic fumes under fire conditions.		
<b>Solubility</b>	: Freely soluble in water.		

## Section 10. Stability and Reactivity

<b>Reactivity</b>	: Not available.
<b>Chemical Stability</b>	: The product is stable.
<b>Possibility of hazardous reactions</b>	: Not available.
<b>Hazardous decomp. products</b>	: When heated to decomposition material emits toxic fumes.
<b>Incompatible materials/Conditions to avoid</b>	: Not available.

## Section 11. Toxicological Information

**Information on the likely routes of exposure** : Inhalation. Injection.

**Toxicity data** : LD50: Not available.

**Delayed and immediate effects and also chronic effects from short and long term exposure** : Possible hypersensitization.  
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. No long-term animal carcinogenicity studies have been conducted with cefepime.  
Reproductive and Developmental Effects: Pregnancy Category: B. Cefepime was not teratogenic or embryocidal when administered during the period of organogenesis to rats at doses up to 1000 mg/kg/day (4 times the recommended maximum human dose calculated on a mg/m<sup>2</sup> basis) or to mice at doses up to 1200 mg/kg (2 times the recommended maximum human dose calculated on a mg/m<sup>2</sup> basis) or to rabbits at a dose level of 100 mg/kg (approximately equal to the recommended maximum human dose calculated on a mg/m<sup>2</sup> basis).  
No untoward effects on fertility or reproduction have been observed in rats, mice, and rabbits when cefepime is administered subcutaneously at 1 to 4 times the recommended maximum human dose calculated on a mg/m<sup>2</sup> basis.

Mutagenicity: A battery of in vivo and in vitro genetic toxicity tests, including the Ames Salmonella reverse mutation assay, CHO/HGPRT mammalian cell forward gene mutation assay, chromosomal aberration and sister chromatid exchange assays in human lymphocytes, CHO fibroblast clastogenesis assay, and cytogenetic and micronucleus assays in mice were conducted. The overall conclusion of these tests indicated no definitive evidence of genotoxic potential.

**Remark**

Not available.

**Symptoms related to the physical, chemical and toxicological characteristics** : Adverse effects may include: local reactions (phlebitis, pain and/or inflammation and rash), colitis, diarrhea, fever, headache, nausea, oralmoniliasis, pruritus, urticaria, vaginitis and vomiting.

## Section 12. Ecological Information

**Ecotoxicity** : Not available.

**Persistence and degradability** : Not available.

**Bioaccumulative potential** : Not available.

**Mobility in soil** : Not available.

**Other adverse effects** : Not available.

## Section 13. Disposal Considerations

**Waste Disposal** : Follow all appropriate safe work procedures and federal, provincial and local regulations for disposal.

**Section 14. Transport information**

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
TDG- road Canada/U.S.			Not regulated.		
ICAO/IATA			Not regulated.		
IMDG Class			Not regulated.		

**Section 15. Regulatory Information**

**Canada** : Covered by Food & Drug Act and therefore not regulated under WHMIS

**Regulations**

Not on the DSL list.

**Other Regulations** : Not available.

**Section 16. Other Information**

**References** : Apotex Monograph

**Revision date:** 7/11/2017

**Notice to Reader**

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