



SAFETY DATA SHEET

Cefepime, USP




1) PRODUCT AND COMPANY IDENTIFICATION

Product Identifier:	Cefepime for Injection, USP
Common/Trade Name:	Maxipime
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, 7 ₂ -(Z)-(O-methyloxime), monohydrochloride, monohydrate
Chemical Family:	Cephalosporin
Product Use:	Antibiotic
Product Type:	Regulated Prescription Drug
Container Information:	Vial
Manufacturer:	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA, 18017
Important Phone Numbers:	Customer Service: 610-974-9760 x 510 E-Mail: pcccustomerconnect@piramal.com 24 Hour Emergency: 484-895-5734

CHEMTREC 1-800-424-9300 (For Transportation in US and Canada.)

2) HAZARDS IDENTIFICATION

(a) Classification:	<u>U.S. OSHA GHS Classification:</u> Eye Irritation (Category 2B) Sensitization – Respiratory (Category 1) Sensitization – Skin (Category 1) Specific Target Organ Toxicity (Category 2)
----------------------------	--

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:			
<p><u>U.S. OSHA GHS Classification:</u></p> <p>Hazard Class</p> <p>Hazard Category</p> <p>Signal Word</p> <p>Symbol</p>	<p>Eye Irritation</p> <p>2B</p> <p>Warning</p> <p>N/A</p>	<p>Sensitization – Respiratory – 1</p> <p>Danger</p> 	<p>Sensitization – Skin 1</p> <p>Warning</p> 	<p>STOT- RE (Specific Target Organ Toxicity, Repeated Exposure) 2</p> <p>Warning</p> 
Hazard Statements:	Causes eye irritation	May cause allergy or asthma symptoms or breathing difficulties if inhaled	May cause an allergic skin reaction	May cause damage to the gastrointestinal system, skin, blood, liver, and kidneys through prolonged or repeated exposure
Precautionary Statements:	<ul style="list-style-type: none"> - Wear protective gloves. - Do not breathe dust. Do not breathe vapor or spray. - In case of inadequate ventilation, wear respiratory protection - Wash thoroughly after handling - Contaminated work clothing must not be allowed out of the workplace 			

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Response:	<ul style="list-style-type: none"> - If on skin: Wash with plenty of water. If skin irritation or rash occurs: get medical advice/attention. Wash contaminated clothing before reuse - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Get medical attention if you feel unwell - If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: call a poison center/doctor

(d) Unknown Acute Toxicity: N/A

3) COMPOSITION/INFORMATION ON INGREDIENTS

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
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, 7 ₂ -(Z)-(O-methyloxime), monohydrochloride,	Cefepime Hydrochloride	62%	123171-59-5	N/A
L-arginine	L-arginine	38%	74-79-3	N/A

4) FIRST AID MEASURES

- Eye Exposure:** Flush eyes with large volumes of water for 15 minutes or more. Seek medical attention if irritation or signs of exposure are noted.
- Skin Exposure:** Remove contaminated clothing, wash skin with water and soap for 15 minutes. Seek medical attention if irritation or signs of exposure are noted.
- Ingestion:** Do not induce vomiting. If ingestion occurs, flush mouth with water and seek medical attention if any symptoms appear.
- Injection:** In cases of accidental injection, wash and disinfect area, seek medical attention.
- Inhalation:** If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

5) FIRE FIGHTING MEASURES

- (a) **Extinguishing Media** Water spray or multi-purpose ABC extinguisher. Fight larger fires with water spray or alcohol resistant foam.
- (b) **Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, hydrogen chloride, oxides of nitrogen, and sulfur oxides.
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

6) ACCIDENTAL RELEASE MEASURES

- Spill:** Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state or local regulations.
- Release to Air:** If aerosolized, reduce exposures by ventilating area. Clean up immediately to prevent evaporation. Wear respiratory protection as necessary.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

7) HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Protect from light, avoid excessive heat, sparks or flames. Store at controlled room temperature 20°–25° C (68°–77° F). Follow instructions provided in packaging.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Cefepime Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

Respiratory Protection:	Under normal use, respirators should not be required if adequate ventilation is available. A dust/mist respirator (N95) may be necessary if aerosols are generated.
Eye Protection:	Chemical goggles and/or face shield. Safety glasses are always required.
Skin Protection:	Work uniform or laboratory coat.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking or smoking when handling this product.

9) PHYSICAL AND CHEMICAL PROPERTIES

(a)	Appearance	white to pale yellow powder
(b)	Odor	None
(c)	Odor Threshold	None
(d)	pH	4-6 after reconstitution
(e)	Melting Point:	Not Available
(f)	Initial Boiling Point:	Not Available
(g)	Flash Point	Not Available
(h)	Evaporation Rate:	Not Available
(i)	Flammability	Not Available
(j)	Upper Lower Flammability or Explosion Limits	Not Available
(k)	Vapor Pressure:	Not Available
(l)	Vapor Density:	Not Available
(m)	Relative Density	Not Available
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not Available
(p)	Auto-ignition Temperature	Not Available
(q)	Decomposition Temperature	Not Available
(r)	Viscosity	Not Available

10) STABILITY AND REACTIVITY

(a)	Reactivity	Not Available
(b)	Chemical Stability	Stable at normal temperature and pressures.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization not anticipated to occur with this product
(d)	Conditions to Avoid	Protect from light
(e)	Incompatible Materials	Not Available

(f) Hazardous Decomposition Products	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), sodium oxides (Na ₂ O), sulfur oxides (SO _x), and hydrogen chloride
---	---

11) TOXICOLOGICAL INFORMATION

(a) Likely Routes of Exposure	May be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Cefepime for Injection, USP presents little hazard.
(b) Symptoms related to the physical, chemical and toxicological characteristics	May cause irritation to eyes, skin, and respiratory tract.
(c) Delayed and immediate effects and also chronic effects from short and long term exposure	Acute signs and symptoms of exposure may include eye, skin, and respiratory irritation.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Cefepime for Injection	LD ₅₀	IV	Mouse	1500 - 2000 mg/kg
	LD ₅₀	Oral	Rat	1,272 mg/kg
	LD ₅₀	IV	Dog	> 2000 mg/kg

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

12) ECOLOGICAL INFORMATION

(a)	Ecotoxicity	For Cefepime L-Arginine: Daphnia magna (Water Flea) EC50 = 640 mg/L (study was conducted on a different salt form)
(b)	Persistence and degradability	Not Available
(c)	Bioaccumulative potential	Not Available
(d)	Mobility in soil	Not Available
(e)	Other Adverse Effects	Not Available

13) DISPOSAL CONSIDERATIONS

Refer to local, state, and federal rules. Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Incineration at an approved, permitted facility is recommended.

14) TRANSPORT INFORMATION

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15) REGULATORY INFORMATION

U.S. Regulations:

TSCA - Not on this list

RCRA – Not on this list

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

California Proposition 65 – Not available

16) OTHER INFORMATION

Piramal provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. PIRAMAL MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, PIRAMAL WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

SDS Updates:

04-15-2019 – New Document