

# SAFETY DATA SHEET



## Ceftriaxone, USP

### 1) PRODUCT AND COMPANY IDENTIFICATION

<b>Product Identifier:</b>	Ceftriaxone for Injection, USP
<b>Common/Trade Name:</b>	Ceftriaxone for Injection, USP
<b>Chemical Name:</b>	(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-[[[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo- <i>as</i> -triazin-3-yl)thio]methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7 <sup>2</sup> -(Z)-(O-methyloxime), disodium salt, sesquaterhydrate
<b>Chemical Family:</b>	Cephalosporin
<b>Product Use:</b>	Antibiotic
<b>Product Type:</b>	Regulated Prescription Drug
<b>Container Information:</b>	Glass vials
<b>Manufacturer:</b>	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA, 18017
<b>Important Phone Numbers:</b>	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


<b>(a) Classification:</b>	<b><u>GHS Classifications:</u></b> Skin irritation (Category 2) Eye irritation (Category 2A) Respiratory sensitisation (Category 1) Skin sensitisation (Category 1) Specific target organ toxicity - single exposure (Category 3), Respiratory system
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#### HMIS Rating

Health Hazard	2
Flammability	0
Physical Hazard	0

#### NFPA Rating

Health Hazard	2
Fire Hazard	0
Reactivity Hazard	0

<b>(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):</b>	<b>(c) Description of Hazards:</b>
<p><u>Signal Word:</u> <u>Symbols:</u></p>	<p>- DANGER</p> 
<p>H315 H317 H319 H334 H335</p>	<p><b><u>GHS Hazard Statements:</u></b></p> <ul style="list-style-type: none"> <li>- Causes skin irritation</li> <li>- May cause an allergic skin reaction</li> <li>- Causes serious eye irritation</li> <li>- May cause allergy or asthma symptoms or breathing difficulties if inhaled</li> <li>- May cause respiratory irritation</li> </ul>
<p>P261 P264 P271 P272  P280 P285 P302 + P352 P304 + P340  P305 + P351 + P338  P321  P333 + P313 P337 + P313 P342 + P311  P362 P402 + P233  P405 P501</p>	<p><b><u>GHS Precautionary Statements:</u></b></p> <ul style="list-style-type: none"> <li>- Avoid breathing dust/fume/gas/mist/vapors/spray</li> <li>- Wash skin thoroughly after handling</li> <li>- Use only outdoors or in a well-ventilated area</li> <li>- Contaminated work clothing should not be allowed out of the workplace</li> <li>- Wear protective gloves/eye protection/face protection</li> <li>- In case of inadequate ventilation wear respiratory protection</li> <li>- IF ON SKIN: Wash with plenty of soap and water</li> <li>- IF INHALED: Removed victim to fresh air and keep at rest in a position comfortable for breathing</li> <li>- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>- Specific treatment (see supplemental first aid instructions on this label)</li> <li>- If skin irritation or rash occurs: Get medical advice/attention</li> <li>- If eye irritation persists: Get medical advice/attention</li> <li>- If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician</li> <li>- Take off contaminated clothing and wash before reuse</li> <li>- Store in a well-ventilated place. Keep container tightly closed.</li> <li>- Store locked up.</li> <li>- Dispose of contents/container to an approved waste disposal plant.</li> </ul>

**(d) Unknown Acute Toxicity N/A**

**3) COMPOSITION/INFORMATION ON INGREDIENTS**

<b>(a) Chemical Name</b>	<b>(b) Common Name / Synonym</b>	<b>% Composition or other measure</b>	<b>(c) CAS No.</b>	<b>(d) Impurities / Stabilizing Additives</b>
(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-[[[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo- <i>as</i> -triazin-3-yl)thio]methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7 <sup>2</sup> -(Z)-(O-methyloxime), disodium salt, sesquaterhydrate	Ceftriaxone sodium	100%	104376-79-6	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:** If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.
- 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** Use foam or all purpose dry chemicals to extinguish.
- (b) Hazardous Combustion Products:** Toxic and corrosive fumes of NO<sub>x</sub> and SO<sub>x</sub>
- (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**

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- 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**

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- 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. Store powder at 20°-25°C (68°-77°F). [See USP Controlled Room Temperature]. Follow instructions provided in packaging.

**8) EXPOSURE CONTROLS/PERSONAL PROTECTION****(a) Exposure Limits**

Compound	Issuer	Type	Exposure Limit
Ceftriaxone	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	0.6 mg/m <sup>3</sup> (4 x 30 min)

**(b) Engineering Controls**

Ventilation: Handle product in a well ventilated area.

**(c) Individual Protection Measures**

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

Respiratory Protection:	Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode. Use chemical resistant, impervious gloves.
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)	<b>Appearance</b>	Solid crystalline powder. Light yellow to amber
(b)	<b>Odor</b>	Practically Odorless
(c)	<b>Odor Threshold</b>	None
(d)	<b>pH</b>	6.0 – 8.0 (100 mg/mL)
(e)	<b>Melting Point:</b>	> 155°C with decomposition
(f)	<b>Initial Boiling Point:</b>	Not available
(g)	<b>Flash Point</b>	Not available
(h)	<b>Evaporation Rate:</b>	Not available
(i)	<b>Flammability</b>	Not available
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Not available

<b>(k)</b>	<b>Vapor Pressure:</b>	Not available
<b>(l)</b>	<b>Vapor Density:</b>	Not available
<b>(m)</b>	<b>Relative Density</b>	Not available
<b>(n)</b>	<b>Solubility(ies)</b>	470,000 mg/L in water (22°C) 32,000 mg/L in methanol (22°C) 200 mg/L in acetone (22°C)
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	Not available
<b>(p)</b>	<b>Auto-ignition Temperature</b>	Not available
<b>(q)</b>	<b>Decomposition Temperature</b>	Not available
<b>(r)</b>	<b>Viscosity</b>	Not available

#### 10) STABILITY AND REACTIVITY

<b>(a)</b>	<b>Reactivity</b>	Not Available
<b>(b)</b>	<b>Chemical Stability</b>	Stable under recommended storage conditions.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	Hazardous polymerization will not occur
<b>(d)</b>	<b>Conditions to Avoid</b>	Avoid storage next to strong oxidizers.
<b>(e)</b>	<b>Incompatible Materials</b>	None identified
<b>(f)</b>	<b>Hazardous Decomposition Products</b>	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), sodium oxides (Na <sub>2</sub> O), and sulfur oxides (SO <sub>x</sub> )

#### 11) TOXICOLOGICAL INFORMATION

<b>(a)</b>	<b>Likely Routes of Exposure</b>	Skin. Inhalation. Ingestion. Eye contact.
<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	May cause eye and skin irritation. May cause allergic reaction.  Practically non-toxic if swallowed. Hypersensitivity (may include drug fever, rash, itching, anaphylaxis). Blood effects (may include increase in eosinophils, neutrophils, and platelets). Gastrointestinal effects (may include

<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Liver function effects (may include increased level of SGOT, SGPT, serum LDH, jaundice). Renal function effects (may include increased level of creatinine, BUN, renal failure). Nervous system effects (headache, dizziness, light headedness).
<b>(c)</b>	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	Acute signs and symptoms of exposure may include eye, skin, and respiratory irritation. May cause nausea, vomiting, abdominal pain, headache, dizziness, light headedness, or skin rash.

**(d) Acute Toxicity**

<b>Component</b>	<b>Type</b>	<b>Route</b>	<b>Species</b>	<b>Dosage</b>
Ceftriaxone sodium	LD <sub>50</sub>	Oral	Mouse	>10 g/kg
Ceftriaxone sodium	LD <sub>50</sub>	Oral	Rat	>10 g/kg
Ceftriaxone sodium	LD <sub>50</sub>	Intravenous	Mouse	2.8 g/kg
Ceftriaxone sodium	LD <sub>50</sub>	Intravenous	Rat	2 g/kg
Ceftriaxone sodium	LD <sub>50</sub>	Intravenous	Rabbit	240 mg/kg

**(e) Hazardous Chemical Listings**

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

**12) ECOLOGICAL INFORMATION**

<b>(a)</b>	<b>Ecotoxicity</b>	Not available
<b>(b)</b>	<b>Persistence and degradability</b>	Not available
<b>(c)</b>	<b>Bioaccumulative potential</b>	Not available
<b>(d)</b>	<b>Mobility in soil</b>	Not available
<b>(e)</b>	<b>Other Adverse Effects</b>	Not available

**13) DISPOSAL CONSIDERATIONS**

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**14) TRANSPORT INFORMATION**

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

**DOT:** Not regulated

**ICAO/IATA:** Not regulated

**IMDG:** Not regulated

**15) REGULATORY INFORMATION****U.S. Regulations:**

TSCA: No

RCRA: Not Listed

CERCLA: Not on this list

SARA 302: Not on this list

SARA 313: Not on this list

SARA 311/312: Acute Health Hazard

OSHA Substance Specific: No

Massachusetts Right to Know Components – Not listed

Pennsylvania Right to Know Components – Ceftriaxone Disodium Salt (CAS No. 104376-79-6)

New Jersey Right to Know Components – Ceftriaxone Disodium Salt (CAS No. 104376-79-6)

California Proposition 65 – Not Listed



## **16) OTHER INFORMATION**

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SDS Updates:  
05-20-2019 – New Document