



# Safety Data Sheet (SDS)

## Ceftriaxone for Injection, USP

### 1 IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

**Product Name:** Ceftriaxone for Injection, USP

**Distributed By:** WG Critical Care, LLC  
120 Route 17 North  
Suite 115  
Paramus, NJ 07652 USA

**Customer Service Phone Number:** 1-888-493-0861  
**Emergency Phone Number:** 1-866-562-4708 (ProPharma)

**Product Use:** Anti-infective  
**Product Type:** Prescription Drug  
**Container Information:** Glass Vials

### 2 HAZARDS IDENTIFICATION

**Classification of Substance or Mixture:** SKIN CORROSION/IRRITATION - Category 2  
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A  
RESPIRATORY SENSITIZATION - Category 1  
SKIN SENSITIZATION - Category 1  
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

**PRIMARY PHYSICAL AND HEALTH HAZARDS:**  
May cause irritations to the skin and eyes. May cause allergic reactions.

**ROUTES OF ENTRY:**  
Skin. Inhalation, Ingestion. Eye.

**SIGNS & SYMPTOMS OF EXPOSURE:**  
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.

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**Label Elements:**


Product Identifier  
 Contains Ceftriaxone sodium  
 Signal Word  
 Danger

Hazard Statements  
 H317 - May cause an allergic skin reaction  
 H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements - EU (§28, 1272/2008)  
 P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
 P280 - Wear protective gloves  
 P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing  
 P321 - Specific treatment (see supplemental first aid instructions on this label)  
 P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor  
 P501 - Dispose of contents/ container to an approved waste disposal plant

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

**SUBSTANCE OR MIXTURE:**

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Ceftriaxone Sodium	100	104376-79-6

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

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### 4 FIRST AID MEASURES

#### Description of first aid measures

<b>GENERAL:</b>	Treat symptomatically and supportively.
<b>INHALATION:</b>	If there is breathing difficulty, remove from exposure and administer oxygen. See medical attention immediately.
<b>EYES:</b>	Flush eyes with water for 10-20 minutes. Seek medical attention.
<b>SKIN:</b>	Remove contaminated clothing wash skin for 15-20 minutes with soap and water. Seek medical attention.
<b>INGESTION:</b>	Do NOT induce vomiting. Flush mouth with water and seek medical attention immediately.

#### OVERVIEW:

<b>Indication of any immediate medical attention and special treatment needed:</b>	<p>in case of strong sensitization against Cephalosporines anaphylaxis and asthma are possible:</p> <p>weak cases:</p> <ul style="list-style-type: none"> <li>- Antihistamine i.v.</li> <li>- in case of asthma topical steroids and inhalative <math>\beta</math>-Mimetica</li> </ul> <p>severe cases:</p> <ul style="list-style-type: none"> <li>- Adrenalin 0.3 - 0.5 mg i.v.</li> <li>- Antihistamine i.v.</li> <li>- high dosage of steroids i.v.</li> <li>- in case of asthma additional inhalation with topical steroids and <math>\beta</math>-Mimetica</li> </ul>
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### 5 FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Water Spray, carbon dioxide, dry powder. Do not use a heavy stream of water.
<b>Special hazards arising from the substance or mixture:</b>	When heated to decomposition material, it emits toxic fumes: carbon monoxide, carbon dioxide, nitrogen oxides, sulfur compounds.

### 6 ACCIDENTAL RELEASE MEASURE

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental precautions</b>	Do not allow to enter drains or waterways.
<b>Methods and material for containment and cleaning up</b>	Collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers. Clean contaminated area/containers with an alkaline cleaner.

### 7 HANDLING AND STORAGE

<b>Precautions for safe handling</b>	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. Keep away from sources of ignition.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).
<b>Specific end use(s)</b>	None

### 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

#### EXPOSURE CONTROLS

<b>Respiratory:</b>	If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
<b>Eyes:</b>	Chemical goggles and/or face shield. Safety glasses are always required.
<b>Skin:</b>	Work uniform or laboratory coat.
<b>Engineering Controls:</b>	Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
<b>Other Work Practices:</b>	None

### 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE:</b>	Solid	<b>APPEARANCE:</b>	White to yellowish orange crystalline powder
<b>UPPER FLAMMABILITY LIMIT:</b>	No data available	<b>LOWER FLAMMABILITY LIMIT:</b>	No data available
<b>EXPLOSIVE LIMITS:</b>	No data available	<b>ODOR:</b>	None to faint
<b>VAPOR PRESSURE:</b>	No data available	<b>ODOR THRESHOLD:</b>	No data available
<b>VAPOR DENSITY:</b>	No data available	<b>pH:</b>	6.0 – 8.0
<b>RELATIVE DENSITY:</b>	No data available	<b>MELTING POINT:</b>	>155°C (decomposes)
<b>FREEZING POINT:</b>	No data available	<b>SOLUBILITY:</b>	Freely soluble in water
<b>INITIAL BOILING POINT:</b>	No data available	<b>BOILING RANGE:</b>	No data available
<b>FLASH POINT:</b>	No data available	<b>EVAPORATION RATE:</b>	No data available
<b>FLAMMABILITY:</b>	No data available	<b>PARTITION COEFFICIENT (N-OCTANOL / WATER)</b>	log Pow = 0.025 (octanol/water) pH 2.0
<b>AUTO-IGNITION TEMPERATURE:</b>	No data available	<b>DECOMPOSITION TEMPERATURE:</b>	No data available
<b>VISCOSITY:</b>	No data available		

### 10 STABILITY AND REACTIVITY

<b>Reactivity:</b>	No known reactivity hazard under normal conditions.
<b>Chemical Stability</b>	Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).
<b>Possibility of Hazardous reactions:</b>	Hazardous polymerization will not occur.
<b>Conditions to avoid:</b>	Contact with strong oxidizing agents.
<b>Incompatible Materials:</b>	Avoid exposure to light, heat and strong oxidizing agents.
<b>Hazardous decomposition products:</b>	When heated to decomposition material, it emits toxic fumes: carbon monoxide, carbon dioxide, nitrogen oxides, sulfur compounds.

### 11 TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY

COMPONENT	Oral LD50, mg/kg	Oral LD50, mg/kg	Intravenous (mouse)	Intravenous (rat)	Intravenous (rabbit)
Ceftriaxone Sodium	>10g/kg (mouse)	>10g/kg (rat)	2.8g/kg	2g/kg	240mg/kg

Note: As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

Oral Toxicity: Not expected to be toxic following ingestion.

Inhalation Toxicity: Can cause allergic reaction.

Skin Effects: Irritation might occur following direct contact.

Eye Effects: Irritation might occur following direct contact with eyes.

Gastrointestinal Reactions: Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps and loss of appetite.

Hypersensitivity Reactions: Rash may occur. Conditions aggravated: Hypersensitivity to penicillin and other antibiotics.

Genetic Toxicity: Not expected to be genotoxic based on animal studies.

Carcinogenicity: Not expected to be carcinogenic based on animal studies.

Reproductive Effects: Not expected to produce adverse effects on fertility or development based on animal studies. No adequate and well controlled studies in pregnant women. No studies during labor and delivery. Should be used during pregnancy only if clearly needed. Since this material has been shown to be excreted in breast milk, nursing mothers should exercise caution regarding exposure.

Pharmacological Effects: This material is an antibiotic; a cephalosporin. It is an agent intended for the treatment of bacterial infections.

## 12 ECOLOGICAL INFORMATION

### Toxicity

#### 12.1. Toxicity

No information available.

#### 12.2. Persistence and degradability

No information available.

#### 12.3. Bioaccumulative potential

No information available.

#### 12.4. Mobility in soil

No information available.

#### 12.5. Results of PBT and vPvB assessment

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

#### 12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Inherent biodegradability - not inherently biodegradable

0 %, 28 days

(MITI Test II, OECD No. 302 C)

Ecotoxicity strongly toxic for microorganisms (activated sludge)

LC0 10 mg/l

-

barely toxic for fish (rainbow trout)

LC0 > 1000 mg/l

-

barely toxic for planktonic crustaceans (*Daphnia magna*)

EC50 (48 h) > 100 mg/l

NOEC (48 h) 86 mg/l

(OECD No. 202)

-

barely toxic for algae (*Selenastrum capricornutum*)

EbC50 (72 h) > 100 mg/l

ErC50 (72 h) > 100 mg/l

NOEC (72 h) 100 mg/l

(OECD No. 201)

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Air pollution - observe local/national regulations

Note - highly active substance

- avoid any contamination of the environment

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### 13 DISPOSAL CONSIDERATIONS

<b>Waste treatment methods</b>	Waste disposal must be in accordance with appropriate Federal, State, and local regulations.
<b>Contaminated Packaging</b>	In accordance with local and national regulations.

### 14 TRANSPORT INFORMATION

**REGULATORY ORGANIZATIONS:**

**DOT:** Not Regulated

**ICAO / IATA:** Not Regulated

**IMO:** Not Regulated

### 15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

**US Regulations**

TSCA – No

CERCLA - No

SARA 302 – No

SARA 313 – No

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

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### 16 OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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