

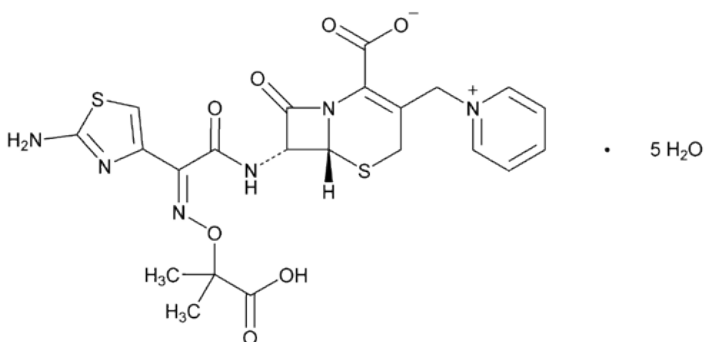
1. PRODUCT AND COMPANY INFORMATION

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

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

Active Ingredient/Primary Component: Ceftazidime

Structure:



Chemical Name: Pyridinium, 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]pyridinium hydroxide, inner salt, 72-(Z)-[O-(1-carboxy-1-methylethyl)oxime], pentahydrate

Molecular Formula: C₂₂H₂₂N₆O₇S₂·5H₂O

UNII Code: UNII-9M416Z9QNR; UNII-DZR1ENT301 [anhydrous].

CAS Number: CAS-78439-06-2; CAS-72558-82-8 [anhydrous]

Chemical Family: Antibiotic

Product Use: Pharmaceutical

Product Type: Prescription Drug

Container Information: Vials

Customer Service Phone Number: +1-888-493-0861

Emergency Phone Number: +1-866-562-4708 (Prosar)

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2. HAZARDS IDENTIFICATION

PRIMARY PHYSICAL AND HEALTH HAZARDS: May cause eye irritation. May cause allergic reaction

ROUTES OF ENTRY: Skin, Inhalation

SIGNS & SYMPTOMS OF EXPOSURE: None reported, however based on prior experience with cephalosporin antibiotics, allergic reactions might be expected, including rash, nasal congestion, cough, dry throat, eye irritation, or anaphylactic shock. Dilute formulations of sodium carbonate may be irritating to the eyes.

CHEMICAL LISTED AS CARCINOGEN: **NTP:** NO **IARC:** NO **OSHA:** NO

3. COMPOSITION / INFORMATION ON INGREDIENTS

| <u>Ingredient</u> | <u>Weight %</u> | <u>CAS No.</u> |
|------------------------------|-----------------|----------------|
| Ceftazidime Pentahydrate | 88-90 | 78439-06-2 |
| Sodium Carbonate Monohydrate | 10-12 | 5968-11-6 |

4. FIRST AID MEASURES

EYE EXPOSURE: Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 to 20 minutes, keeping eyelids open. Seek immediate medical attention.

SKIN EXPOSURE: . Remove contaminated clothing, wash skin with water and mild 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. Do not give anything by mouth to an unconscious person.

INHALATION: If inhaled, remove to fresh air. If breathing becomes difficult, call a physician immediately. If breathing has stopped, give artificial respiration and seek immediate medical attention.

NOTE TO PHYSICIAN: See patient package insert in shipping carton for complete information.

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5. FIRE FIGHTING MEASURES

| | |
|--|--|
| FLASH POINT: | Not applicable |
| AUTO-IGNITION TEMPERATURE: | Not applicable |
| FLAMMABLE LIMITS IN AIR: | Not applicable |
| FLAMMABLE LIMITS: | Not applicable |
| EXTINGUISHING MEDIA: | Use water spray, alcohol-resistant foam, dry chemicals, or carbon dioxide. |
| UNUSUAL FIRE / EXPLOSION HAZARDS: | May emit toxic fumes when exposed to heat or fire. |

6. ACCIDENTAL RELEASE MEASURE

| | |
|--------------------------|--|
| SPILL: | Wear protective equipment, including eye protection, to avoid exposure. Absorb liquid with suitable material according to the applicable federal, state, or local regulations. Collect and place it in a suitable, properly labeled container for recovery or disposal |
| 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: | Wash thoroughly after handling. Avoid skin contact. Avoid eye contact |
| STORAGE CONDITIONS: | Refrigerate 2°C to 8°C (36°F to 46°F). Keep in a dry place. |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---|---|
| RESPIRATORY PROTECTION: | Use an approved respirator. |
| EYE PROTECTION: | Chemical goggles and/or face shield. Safety glasses are always required. |
| VENTILATION: | Handle product in a well-ventilated area. Laboratory fume hood or local exhaust ventilation. |
| SKIN PROTECTION: | Wear uniform or laboratory coat. |
| OTHER PROTECTIVE EQUIPMENT: | Chemical-resistance gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respiratory and goggles or face shield may not be required. Safety glasses are always required |
| ADDITIONAL EXPOSURE PRECAUTIONS: | In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs. Wash hands following use. No eating, drinking, or smoking when handling this product. |

9. PHYSICAL AND CHEMICAL PROPERTIES

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|---|--|
| PHYSICAL STATE: Solid | SPECIFIC GRAVITY: Not available |
| APPEARANCE AND ODOR: White to off-white crystalline powder; in solution can range from yellow to amber | EVAPORATION RATE: Not available |
| BOILING POINT: Not available | MELTING POINT: Not available |
| VAPOR PRESSURE: Not available | SOLUBILITY IN WATER: Soluble |
| VAPOR DENSITY: Not available | pH: 5.0 – 7.5 |

10. STABILITY AND REACTIVITY

| | |
|--|---|
| STABILITY: | Stable under recommended storage conditions |
| INCOMPATIBILITY (MATERIALS TO AVOID): | May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.) and strong acids |
| HAZARDOUS POLYMERIZATION: | Will not occur |
| HAZARDOUS DECOMPOSITION: | May emit toxic fumes when heated to decomposition. |
| CONDITIONS TO AVOID: | Not available |

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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

| COMPONENT | LD50 Dermal | LC50 Inhalation | LD50 Oral |
|------------------------------|--------------------|-----------------|------------------|
| Ceftazidime Pentahydrate | - | - | - |
| Sodium Carbonate Monohydrate | 2210 mg/kg (mouse) | | 4090 mg/kg (rat) |

*Occasionally hypersensitivity reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and / or a history of sensitivity to multiple allergens.

12. ECOLOGICAL INFORMATION

No applicable ecological information found.
Observe local environmental regulations.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Dispose of any cleanup materials and waste residue according to all applicable laws and 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

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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 SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). 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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