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|  | Sagent Pharmaceuticals, Inc. | | | | |
| | Ceftazidime for Injection | | | Material Safety Data Sheet (MSDS) | |
| | Issue Date: | MSDS No.: MSDS 007 | Version No.: 1.0 | Form Number: R-SOP-009-F001 | Page: 1 of 8 |

Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier:

Ceftazidime for Injection, USP

Product Code:

NDC 25021-127-20
NDC 25021-128-50
NDC 25021-129-99

Common/Trade Name:

Ceftazidime

Chemical Name:

Pyridinium, 1-[[7-[[2-amino-4-thiazolyl][1-carboxy-1-methylethoxy)imino]acetyl]amino-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-hydroxide, inner salt, [6R-6 α , 7 β (Z)]

Chemical Family:

Antibiotic

Product Use:

Pharmaceutical

Product Type:


Regulated Prescription Drug

Container Information:

Glass vials

Section 2 - Composition / Information on Ingredients

| Ingredient | Concentration % | OSHA PEL | ACGGIH TLV | Other Limits Recommended | CAS No. |
|------------------------------|-----------------|----------|------------|--------------------------|------------|
| Ceftazidime Pentahydrate | 88-90 | None | None | None | 78439-06-2 |
| Sodium Carbonate Monohydrate | 10-12 | None | None | None | 5968-11-6 |


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Section 3 - Hazards Identification

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|---|---|
| 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 |
| Medical Conditions Generally Aggravated by Exposure: | Hypersensitivity to penicillin or cephalosporin. |

Section 4 - First Aid Measures

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| 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. |


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Section 5 - Fire Fighting Measures

| | |
|--|--|
| Flash Point | Not Applicable |
| Autoignition Temperature: | Not Applicable |
| Flammable Limits in Air | Lower %: Not Applicable Upper %: Not Applicable |
| Flammable Limits: | Not Applicable |
| Extinguishing Media | Use water, carbon dioxide, foam, all purpose dry chemicals to extinguish or Halon. |
| Special Fire Fighting Procedures: | As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. |
| Unusual Fire/Explosion Hazards: | May emit toxic fumes when exposed to heat or fire. |

Section 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. |

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Section 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.
- Waste Disposal Method:** Refer to local, state, and federal rules.
- Storage Conditions:** No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

Section 8 - Exposure Controls / Personal Protection

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

- 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.
- 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.

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Exposure Limits


| <u>Compound</u> | <u>Issuer</u> | <u>Type</u> | <u>OEL</u> |
|-----------------|---------------|-------------|------------|
| Ceftazidime | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ----- | STEL | NE |

Section 9 - Physical and Chemical Properties

| | | | |
|-----------------------------|---|-----------------------------|-------------------------|
| Physical State: | Solid | Specific Gravity: | Not available |
| Appearance and Odor: | White to cream-colored crystalline powder | Evaporation Rate: | Not available |
| Boiling Point: | Not available | Solubility in Water: | Soluble |
| Vapor Pressure: | Not available | pH: | 5.0 – 7.5 (10% aqueous) |
| Vapor Density: | Not available | | |

Section 10 - Stability and Reactivity

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| Stability: | Stable to normal temperatures and pressures. |
| Incompatibility (Materials to avoid): | May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.) and strong acids. |
| Hazardous Decomposition: | May emit toxic fumes when heated to decomposition. |
| Hazardous Polymerization: | Will not occur. |
| Conditions to Avoid: | Not applicable. |

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Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure:

IMMEDIATE EFFECTS:


Irritating to eyes. May cause sensitization by inhalation and skin contact. Allergic reaction might be expected, including rash, nasal congestion, cough dry throat, or anaphylactic shock.

Acute Exposure

| Component | Type | Route | Species | Dosage |
|----------------------------|------------------|--------------|---------|----------------------------|
| Ceftazidime pentahydrate | LD ₅₀ | Oral | Rat | 500 mg/kg |
| Ceftazidime pentahydrate | LD ₅₀ | Skin | Rabbit | 200 mg/kg |
| Ceftazidime pentahydrate | LD ₅₀ | Inhalation | Rat | 690 mg/m ³ |
| Ceftazidime pentahydrate | LD ₅₀ | Intravenous | Rat | 2581 mg/kg |
| Ceftazidime pentahydrate | LD ₅₀ | Intravenous | Monkey | 1500 mg/kg |
| Ceftazidime pentahydrate | --- | Skin Contact | Rabbit | Solution contact with skin |
| Ceftazidime pentahydrate | --- | Eye Contact | Rabbit | Solution contact with eye |
| Sodium carbonate anhydrous | LD ₅₀ | Inhalation | Rat | 2300 mg/m ³ |
| Sodium carbonate anhydrous | --- | Eye Contact | Rabbit | Solution contact with eye |

Section 12 - Ecological Information

No applicable ecological information found.

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Section 13 - Disposal Considerations

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

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

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

U.S. Regulations

TSCA - *Not on this list*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*


SARA 313 - *Not on this list*

Section 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 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.

For additional information contact:

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

| | |
|------------|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AIHA | American Industrial Hygiene Association |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of 1980) |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| EPA | Environmental Protection Agency |
| HEPA | High Efficiency Particulate Air (Filter) |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport Association |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NIOSH | National Institute for Occupational Safety and Health |
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |