

## 1. Identification

<b>Product identifier</b>	<b>Ceftazidime Pentahydrate</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1098130	
<b>CAS number</b>	78439-06-2	
<b>Chemical name</b>	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, pentahydrate, [6R-[6alpha, 7beta(Z)]]-	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 2B
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Causes eye irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Avoid breathing dust. Wear protective gloves. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. In case of inadequate ventilation wear respiratory protection.	
<b>Response</b>	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 advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	

**Hazard(s) not otherwise classified (HNOC)** This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

**Supplemental information** Pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Ceftazidime Pentahydrate		78439-06-2	100

### 4. First-aid measures

**Inhalation** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

**Skin contact** Wash off with soap and plenty of water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

**Eye contact** Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed** May cause allergic skin reaction. May cause allergic respiratory reaction. Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Treatment of cephalosporin overdose may include the following: Administer activated charcoal as a slurry. For acute hypersensitivity, administer epinephrine and diphenhydramine. Treat seizures with a benzodiazepine IV or barbiturates if needed. Monitor fluid and electrolyte status; for hematologic and renal abnormalities; for hypotension; and for respiratory depression. For coagulopathies, administer Vitamin K Hemodialysis may aid in removal from the blood

**General information** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

**Suitable extinguishing media** Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable extinguishing media** None known.

**Specific hazards arising from the chemical** Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**Special protective equipment and precautions for firefighters** Wear suitable protective equipment.

**Fire fighting equipment/instructions** Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards** No unusual fire or explosion hazards noted.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

**Methods and materials for containment and cleaning up** For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

Industrial Use Material	Type	Value
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Ceftazidime Pentahydrate (CAS 78439-06-2)	STEL	0.1 mg/m <sup>3</sup>
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### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Crystalline powder.

#### Color

White. Cream.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

275 - 278.6 °F (135 - 137 °C)  
294.8 °F (146 °C) (decomposes)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

**Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.

**Vapor pressure** < 0.0000001 kPa at 25 °C

**Vapor density** Not available.

**Relative density** Not available.

**Solubility(ies)**

<b>Solubility (water)</b>	Slightly soluble.
<b>Solubility (other)</b>	Acetone: Insoluble. Chloroform: Insoluble. Dimethylformamide: Slightly soluble. Dimethylsulfoxide: Soluble. Dioxane: Insoluble. Ethanol: Insoluble. Ether: Insoluble. Ethyl acetate: Insoluble. Methanol: Slightly soluble. Toluene: Insoluble.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Other information**

<b>Chemical family</b>	Cephalosporin.
<b>Dust explosion properties</b>	
<b>Kst</b>	184 bar.m/s
<b>St class</b>	1 Weak explosion.
<b>Minimum ignition energy (MIE) - dust cloud</b>	400 - 500 mJ
<b>Molecular formula</b>	C <sub>22</sub> H <sub>22</sub> N <sub>6</sub> O <sub>7</sub> S <sub>2</sub> · 5H <sub>2</sub> O
<b>Molecular weight</b>	636.65
<b>pH in aqueous solution</b>	3 - 4 Solution: 0.5%
<b>Potential for dust explosion</b>	Weak dust explosion.

**10. Stability and reactivity**

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents. Strong acids.

**Hazardous decomposition products** SO<sub>x</sub>, NO<sub>x</sub>. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

**11. Toxicological information****Information on likely routes of exposure**

<b>Inhalation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Skin contact</b>	May cause an allergic skin reaction.
<b>Eye contact</b>	Causes eye irritation.
<b>Ingestion</b>	Knowledge about health hazard is incomplete.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Cephalosporins: Gastrointestinal disturbances. Respiratory difficulties. Sore throat. Vaginal itching. White patches in mouth.

## Information on toxicological effects

### Acute toxicity

Product	Species	Test Results
Ceftazidime Pentahydrate (CAS 78439-06-2)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	> 20 g/kg (anhydrous)
	Rat	> 20 g/kg (anhydrous)
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Causes eye irritation.	
<b>Local effects</b>		
Eye irritation test		
Result: Slightly irritating.		
Species: Rabbit		
Skin irritation test		
Result: Not irritating.		
Species: Rabbit		
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. For cephalosporins: Anaphylaxis has been reported with therapeutic use.	
<b>Skin sensitization</b>	May cause an allergic skin reaction. For cephalosporins: Hypersensitivity reactions have been reported with therapeutic use.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
<b>Mutagenicity</b>		
Ames test		
Result: Negative.		
Micronucleus test		
Result: Negative.		
Species: Mouse		
Mutagenicity, SOS/umu bacterial mutation test		
Result: Positive.		
Severity: DNA damage.		
<b>Carcinogenicity</b>	Knowledge about carcinogenicity is incomplete.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not regulated.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not listed.		
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met. A population-based case control study did not find an association between therapeutic use of cephalosporins during pregnancy and birth defects.	
<b>Reproductivity</b>		
1 - 2 g/kg Reproductivity / Developmental, administered intravenously during gestation.		
Result: No adverse effects on fertility at low dose; delayed skeletal ossification but no defects at high dose.		
Species: Rat		
200 mg/kg Reproductivity / Developmental, administered during gestation.		
Result: Negative: No adverse effects on the fetuses.		
Species: Rabbit		
Reproductivity / Developmental, 40 times the human dose.		
Result: Negative: No adverse effects on fertility or on the fetuses.		
Species: Mouse, Rat		
<b>Specific target organ toxicity - single exposure</b>	Knowledge about health hazard is incomplete.	
<b>Specific target organ toxicity - repeated exposure</b>	Knowledge about health hazard is incomplete.	
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.	
<b>Further information</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.	

## 12. Ecological information

### Ecotoxicity

Product		Species	Test Results
Ceftazidime Pentahydrate (CAS 78439-06-2)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	IC50	Algae	0.025 mg/l, 72 hours
Crustacea	EC50	Daphnia magna	> 106 mg/l, 48 hours
Fish	EC50	Rainbow Trout	> 106 mg/l, 96 hours

<b>Persistence and degradability</b>	Expected to be inherently biodegradable.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (Ceftazidime Pentahydrate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III

### IATA

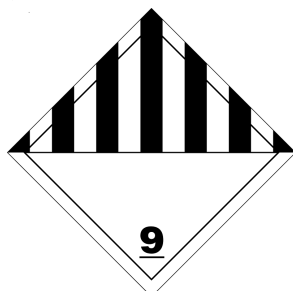
<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (Ceftazidime Pentahydrate)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Other information</b>	

**Passenger and cargo aircraft** Allowed with restrictions.

**Cargo aircraft only** Allowed with restrictions.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

**DOT; IATA**



**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

### US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories

Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - Yes

Pressure Hazard - No

Reactivity Hazard - No

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

Yes

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

### US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date 12-20-2006

Revision date 04-12-2018

Version # 03

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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