

## 1. Identification

<b>Product identifier</b>	<b>Cefprozil</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1098062	
<b>Chemical name</b>	(6R,7R)-7-((R)-2-Amino-2-(p-hydroxyphenyl)acetamido)-8-oxo-3-propenyl-5-thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid monohydrate	
<b>Synonym(s)</b>	Cefprozil monohydrate	
<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>Note</b>	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.	
<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 allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Wash thoroughly after handling. Avoid breathing dust. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.	
<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)** Not classified.

**Other hazards which do not result in classification** None known.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Cefprozil	Cefprozil monohydrate	121123-17-9	100

### 4. First-aid measures

**Inhalation** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin contact** Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.

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

**Most important symptoms/effects, acute and delayed** Irritation of eyes and mucous membranes. May cause allergic skin reaction. May cause allergic respiratory reaction.

**Indication of immediate medical attention and special treatment needed** Treatment of cephalosporin overdose should be symptomatic and supportive and may include the following: Administer charcoal as a slurry. Evaluate patients for signs and symptoms of hypersensitivity. Anaphylaxis should be managed with establishment of a patent airway, epinephrine, and diphenhydramine. For seizures, administer diazepam or lorazepam. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Monitor fluid and electrolyte status in patients with severe vomiting and/or diarrhea. Monitor for renal and hematologic abnormalities. For coagulopathies, vitamin K has been beneficial. (Poisindex)

**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** Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO<sub>2</sub>.

**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.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures** 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. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

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

## 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. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

### 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

### Exposure limit values

#### Industrial Use Material

	Type	Value
Cefprozil (CAS 121123-17-9)	TWA	1 mg/m <sup>3</sup>

### Biological limit values

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

### Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

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

#### Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

#### Skin protection

##### Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

##### Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

#### Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

Yellow powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

3.5 - 6.5

### Melting point/freezing point

411.8 °F (211 °C) (decomposes)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not applicable.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Slightly soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Cephalosporin.
<b>Dust explosion properties</b>	
<b>Kst</b>	165 bar.m/s
<b>St class</b>	1 estimated
<b>Minimum ignition energy (MIE) - dust cloud</b>	80 - 100 mJ
<b>Molecular formula</b>	C18H19N3O5S . H2O
<b>Molecular weight</b>	407.44
<b>Potential for dust explosion</b>	Weak to moderate explosion characteristics if ignited as a dust cloud.
<b>Solubility (other)</b>	Practically insoluble in alcohol.

## 10. Stability and reactivity

<b>Reactivity</b>	Not available.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	None known.
<b>Hazardous decomposition products</b>	NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<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.

**Symptoms related to the physical, chemical, and toxicological characteristics** Cephalosporins: Nausea. Vomiting. Diarrhea. Abdominal pain. Loss of appetite. Heartburn. Dizziness. Agitation. Headache. Fatigue. Fever. Chills. Skin rash. Hives. Trouble breathing. Vaginal itching. White patches in mouth. Bleeding.

**Delayed and immediate effects of exposure** Cephalosporins: Pseudomembranous colitis. Candidiasis. Superinfections. Allergic reaction.

**Cross sensitivity** Persons sensitive to one cephalosporin or cephamycin, or to penicillins, penicillin derivatives, or penicillamine may be sensitive to this material also.

**Medical conditions aggravated by exposure** Cephalosporins: Active alcoholism. Liver or kidney function impairment. Gastrointestinal disease (ulcerative colitis, regional enteritis, antibiotic-associated colitis).

**Acute toxicity** Based on available data, the classification criteria are not met.

Product	Species	Test Results
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Cefprozil (CAS 121123-17-9)

### Acute

#### Oral

LD50	Mouse	> 5000 mg/kg
	Rat	> 5000 mg/kg

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Causes eye irritation.

## Respiratory or skin sensitization

**Respiratory sensitization** May cause allergy or asthma symptoms or breathing difficulties if inhaled. For cephalosporins: Anaphylaxis has been reported with therapeutic use.

**Skin sensitization** May cause an allergic skin reaction. For cephalosporins: Hypersensitivity reactions have been reported with therapeutic use.

**Germ cell mutagenicity** Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

### Mutagenicity

Ames reverse-mutation assay

Result: Negative.

CHO/HGPRT mammalian cell forward mutation assay

Result: Negative.

Chromosome aberration test in vitro

Result: Negative.

DNA repair assay

Result: Negative.

In vivo rat bone marrow cytogenic test

Result: Negative.

**Carcinogenicity** Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

**Reproductive toxicity** Due to lack of data the classification is not possible.

### Reproductivity

250 mg/kg Pre- and Postnatal Development Study

Result: Decreased weight gain in offspring. Maternal effects.

Species: Rat

40 mg/kg Embryo-Fetal Development Study

Result: No significant adverse effects observed.

Species: Rabbit

**Specific target organ toxicity - single exposure** Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure** Due to lack of data the classification is not possible.

**Aspiration hazard** Based on available data, the classification criteria are not met.

## 12. Ecological information

**Ecotoxicity** No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability** Inherently biodegradable.

**Bioaccumulative potential** Not available.

**Mobility in soil** Not available.

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** 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.

**Local disposal regulations** Not available.

**Hazardous waste code** Not regulated.

**Waste from residues / unused products** Dispose of in accordance with local regulations. 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).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

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

## 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### 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

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)** 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.

#### US. California Proposition 65

Not Listed.

### 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** 11-15-2011

**Revision date** 09-08-2015

**Version #** 05

**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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**Revision Information**

Physical & Chemical Properties: Multiple Properties  
GHS: Classification