

1. Identification

Product identifier	Cefprozil (Z)-Isomer	
Other means of identification		
Catalog number	1098050	
Chemical name	(6R,7R)-7-((R)-2-Amino-2-(p-hydroxyphenyl)acetamido)-8-oxo-3-(1Z)propenyl-5-thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid monohydrate	
Synonym(s)	cis-Cefprozil	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

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



Signal word	Danger	
Hazard statement	May cause an allergic skin reaction. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.	
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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 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.	
Storage	Not available.	
Disposal	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 (Z)-Isomer	cis-Cefprozil	114876-72-1	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Skin contact	Wash off with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. 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.
Indication of immediate medical attention and special treatment needed	Treatment of overdose should be symptomatic and supportive. Administer activated charcoal as a slurry. For hypersensitivity reactions, manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia. For dysrhythmias, treat with standard anti-arrhythmic drugs, if necessary. Monitor fluid and electrolyte status. Monitor renal function. Monitor hematologic abnormalities. For coagulopathies, administer Vitamin K. For mild pseudomembranous colitis, treatment is usually not necessary. For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against <i>Clostridium difficile</i> colitis. Hemodialysis may be of benefit. (DrugPoints)
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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

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

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.
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	Form
Cefprozil (Z)-Isomer (CAS 114876-72-1)	TWA	1 mg/m ³	For cefprozil

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 (0.5% aqueous solution)

Melting point/freezing point

424.4 - 428 °F (218 - 220 °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.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family	Cephalosporin.
Molecular formula	C ₁₈ H ₁₉ N ₃ O ₅ S . H ₂ O
Molecular weight	407.44

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Not available.
Hazardous decomposition products	NO _x , SO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

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

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	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 allergic to penicillins, penicillin derivatives, cephalosporins, cephamycins or penicillamine may be allergic 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

Product	Species	Test Results
Cefprozil (Z)-Isomer (CAS 114876-72-1)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg

Skin corrosion/irritation Classification not possible.

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.
Skin sensitization	May cause an allergic skin reaction.

Germ cell mutagenicity Classification not possible.

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 cytogenetic test
Result: Negative.

Carcinogenicity Classification not possible.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity 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.

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

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

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 No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

Local disposal regulations Not available.

Hazardous waste code Not regulated.

Waste from residues / unused products 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 - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

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 12-26-2012

Revision date 09-09-2015

Version # 03

Further information Not available.

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Revision Information Physical & Chemical Properties: Multiple Properties