

1. Identification

Product identifier	Cefoperazone Dihydrate	
Other means of identification		
Catalog number	1097705	
Chemical name	5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino](4-hydroxyphenyl)acetyl]amino]-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-, [6R-[6alpha,7beta (R*)]]-, dihydrate	
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		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
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	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Precautionary statement		
Prevention	Avoid breathing dust. Wear protective gloves. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace.	
Response	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.	
Storage	Not available.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Cefoperazone Dihydrate		113826-44-1	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. 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. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact	Rinse with water. 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	Shortness of breath. Sore throat. Skin itching, rash, or redness.
Indication of immediate medical attention and special treatment needed	Treatment of cephalosporin overdose should be symptomatic and supportive and may include the following: <ol style="list-style-type: none">1. Administer activated charcoal as a slurry.2. For hypersensitivity reactions, manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine.3. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital.4. For dysrhythmias, treat with standard antiarrhythmic drugs, if necessary.5. Monitor fluid and electrolyte status in patients with severe vomiting and/or diarrhea. Monitor renal and hematologic abnormalities.6. For coagulopathies, administer vitamin K.7. For mild pseudomembranous colitis, treatment is usually NOT necessary. For moderate to severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an oral antibacterial drug effective against <i>Clostridium difficile</i>.8. Hemodialysis may slightly aid in elimination of cefoperazone. [Meditext 2007 and USP DI 2007]
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 ₂ .
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	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	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.
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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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to pale buff crystals or crystalline powder.
Physical state	Solid.
Form	Crystalline powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	336.2 - 339.8 °F (169 - 171 °C) (hydrated)
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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.

Viscosity Not available.

Other information

Chemical family Cephalosporin
Molecular formula C₂₅H₂₇N₉O₈S₂.2H₂O
Molecular weight 681.71

10. Stability and reactivity

Reactivity No reactivity hazards known.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid None known.
Incompatible materials None known.
Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NO_x, SO_x.

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 Due to lack of data the classification is not possible.

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 one cephalosporin or cephamycin or to penicillins, penicillin derivatives, 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
Cefoperazone Dihydrate (CAS 113826-44-1)		
Oral		
LD50	Mouse	> 12 g/kg, (anhydrous)
	Rat	> 12 g/kg, (anhydrous)

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

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 Based on available data, the classification criteria are not met. Cefoperazone showed no evidence of mutagenicity in reverse mutation tests in *E. coli* and *S. typhimurium*, in a *B. subtilis* recombination test, and in an intramuscular *S. typhimurium* host-mediated assay in mice. An intravenous dominant lethal test in mice and an intravenous bone marrow cytogenic test in male mice were also 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 Based on available data, the classification criteria are not met. There was no evidence of adverse effects on mating or general reproduction in rats administered cefoperazone doses up to 1000 mg/kg/day prior to and during mating or in females during pregnancy. At all dose levels tested, there were adverse effects in the testes of prepubertal. No birth defects or adverse fetal effects were found in Rhesus monkeys administered cefoperazone at doses up to 400 mg/kg, mice administered doses up to 1000 mg/kg, or rats administered doses up to 1000 mg/kg. A population-based case control study did not find an association between therapeutic use of cephalosporins during pregnancy and birth defects.

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	Not classified.

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	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 available.
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 a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.
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15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA.
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Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

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.
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International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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)

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

Issue date	03-13-2007
Revision date	03-19-2015
Version #	02
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.