

1. Identification

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| Product identifier | Cefotiam Hydrochloride | |
| Other means of identification | | |
| Catalog number | 1098005 | |
| Chemical name | 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(2-amino-4-thiazolyl)acetyl]amino]-3-[[[1-[2-(dimethylamino)ethyl]-1H-tetrazol-5-yl]thio]methyl]-8-oxo-, hydrochloride, (6R-trans)- | |
| 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

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|------------------|----------------------------|------------|--|
| Physical hazards | Not classified. | | |
| Health hazards | Sensitization, respiratory | Category 1 | |
| | Sensitization, skin | Category 1 | |
| OSHA hazard(s) | Not classified. | | |
| Label elements | | | |



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| 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. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. | | |
| 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 | % |
|------------------------|--------------------------|------------|-----|
| Cefotiam Hydrochloride | | 66309-69-1 | 100 |

4. First-aid measures

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| 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. Get medical attention if irritation develops and persists. |
| 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 | 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

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| 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

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| 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

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| 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

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| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Exposure guidelines | No exposure standards allocated. |

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| 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

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| Appearance | White to light yellow crystals. |
| Physical state | Solid. |
| Form | Crystals. |
| Odor | Odorless or faint characteristic odor. |
| Odor threshold | Not available. |
| pH | 1.2 - 1.7 (1 gram in 10 mL of water). |
| Melting point/freezing point | Approximately 97 ° C |
| 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 | Freely soluble. |
| 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 | C ₁₈ H ₂₃ N ₉ O ₄ S ₃ . 2HCl |
| Molecular weight | 598.55 |

Solubility (other)

Soluble in methanol; slightly soluble in ethanol.

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.

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

For cephalosporins: Black, tarry stools. Chest pain. Chills. Cough. Fever. Painful or difficult urination. Shortness of breath. Sore throat. Sores, ulcers, or white spots on lips or in mouth. Swollen glands. Unusual bleeding or bruising. Unusual tiredness or weakness. Abdominal or stomach cramps or pain. Abdominal tenderness. Watery, severe diarrhea which may be bloody. Skin itching, rash, or redness. Hives. Nausea or vomiting. Headache. Indigestion. Flatulence. Loss of appetite. Dizziness. Vaginal itching, infection, or discharge.

Delayed and immediate effects of exposure

Cephalosporins: Pseudomembranous colitis. Candidiasis. Superinfections. Allergic reaction.

Cross sensitivity

Persons sensitive to any cephalosporin or cephamycin, or to any penicillin, penicillin derivative, or penicillamine may be sensitive to this material also.

Medical conditions aggravated by exposure

Active alcoholism. Recent alcohol ingestion. History of bleeding disorders. Impaired kidney function. Gastrointestinal disease.

Acute toxicity**Product****Species****Test Results**

Cefotiam Hydrochloride (CAS 66309-69-1)

Oral

LD50

Rat

> 20 g/kg

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.

Skin sensitization

May cause an allergic skin reaction.

Germ cell mutagenicity

Due to lack of data the classification is not possible.

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. In studies during organogenesis and in the perinatal period at doses up to 3000 mg of cefotiam hexetil hydrochloride there was some reduced fetal weight but no developmental effects in rats.

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**

There are no data on the ecotoxicity of this product.

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

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| 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 | Dispose of in accordance with local regulations. |
| 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.

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 - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical Yes

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.

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) | 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) | Yes |
| 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

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|-----------------------------|--|
| Issue date | 09-13-2010 |
| Revision date | 03-25-2015 |
| Version # | 02 |
| Further information | Not available. |
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