SAFETY DATA SHEET

1. Identification

Product identifier Cefetamet

Other means of identification

Catalog number 1097727 65052-63-3 **CAS** number

Synonyms Desacetoxycefotaxime

Chemical name (6R,7R)-7-[(Z)-2-(2-aminothiazol-4-yl)-2-(methoxyimino)acetamido]-3-methyl-

8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid

Specified quality tests and assay use only. Recommended use

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

U. S. Pharmacopeia Company name **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

CHEMTREC within US & **Emergency phone number** 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards 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. May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves. Contaminated work

clothing must not be allowed out of the workplace. In case of inadequate ventilation wear

respiratory protection.

If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Response

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.

Not available. Storage

Dispose of contents/container in accordance with local/regional/national/international regulations. **Disposal**

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Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Cefetamet	Desacetoxycefotaxime	65052-63-3	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

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact Ingestion

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

Most important

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. May cause allergic skin reaction. May cause allergic respiratory reaction. Pharmacologically active

symptoms/effects, acute and

material. Occupational exposure may cause physiological effects.

delayed

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 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.

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

No unusual fire or explosion hazards noted.

the chemical

Wear suitable protective equipment.

Special protective equipment and precautions for firefighters

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

Cool containers exposed to flames with water until well after the fire is out.

No unusual fire or explosion hazards noted. General fire hazards

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.

Methods and materials for containment and cleaning up 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. For waste disposal, see section 13 of the SDS.

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

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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. 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

No exposure limits noted for ingredient(s).

Biological limit values

Appropriate engineering

controls

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

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

Handle in accordance with good industrial hygiene and safety practice. 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 stateSolid.FormPowder.ColorWhite.

Odor Not available.
Odor threshold Not available.
pH Not available.
Melting point/freezing point Not available.
Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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.

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Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Solubility (other) Methanol: Slightly soluble.

Dimethyl sulfoxde: Slightly soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical familyCephalosporin.Molecular formulaC14H15N5O5S2

Molecular weight 397.43

10. Stability and reactivity

ReactivityThe 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.

Hazardous decomposition

products

NOx, SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact May cause an allergic skin reaction.

Eye contact Knowledge about health hazard is incomplete. **Ingestion** Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics

Cephalosporins: Gastrointestinal disturbances. Respiratory difficulties. Sore throat. Vaginal

itching. White patches in mouth.

Information on toxicological effects

Acute toxicity Not known.

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

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 Knowledge about mutagenicity is incomplete. **Carcinogenicity** Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

A population-based case control study did not find an association between therapeutic use of

cephalosporins during pregnancy and birth defects.

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Reproductivity

0 - 500 mg/kg/day Reproduction study, Cefetamet pivoxil

adminstered orally

Result: No increase in the incidence of malformations.

Species: Rat

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

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

Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential Mobility in soil

No data available. No data available.

Other adverse effects

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

Disposal instructions

Dispose of contents/container in accordance with local/regional/national/international 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 in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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 applicable.

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

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Not listed.

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Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard

Respiratory or skin sensitization

categories

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

Not regulated.

(SDWA)

US state regulations

California Proposition 65

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. For more information go to www.P65Warnings.ca.gov.

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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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
 06-28-2013

 Revision date
 04-15-2020

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