SAFETY DATA SHEET



1. Identification

Product identifier Cephapirin Benzathine

Other means of identification

Catalog number 1102408 **CAS** number 97468-37-6

Chemical name 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid,

3-[(acetyloxy)methyl]-8-oxo-7-[[(4-pyridinylthio)acetyl]amino]-, (6R-trans)-, compound with

N,N'-bis(phenylmethyl) -1,2-ethanediamine (2:1)

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 RSTECH@usp.org E-mail

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

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Not classified. **Physical hazards**

Health hazards Sensitization, respiratory Category 1

> Sensitization, skin Category 1

Environmental hazards Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing **Hazard statement**

difficulties if inhaled.

Precautionary statement

Avoid breathing dust. Contaminated work clothing must not be allowed out of the workplace. Wear Prevention

protective gloves. 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.

Storage Not available.

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

Hazard(s) not otherwise None known.

classified (HNOC)

Material name: Cephapirin Benzathine USP SDS US 1102408 Version #: 04 Revision date: 03-08-2019 Issue date: 02-24-2003

1/6

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Cephapirin Benzathine		97468-37-6	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. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. For minor skin

contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical

advice/attention. Wash clothing separately before reuse.

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

Pharmacologically active material. Occupational exposure may cause physiological effects.

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

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazardsNo unusual fire or explosion hazards noted.

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.

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

Material name: Cephapirin Benzathine USP SDS US

7. Handling and storage

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of Precautions for safe handling

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

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

Appropriate engineering

controls

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

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

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.

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of Other

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.

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face Respiratory protection

respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task

and the level of existing engineering controls.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

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 descriptions are general information and not specific to any USP lot. **Appearance**

Solid. Physical state **Form** Powder.

Color White. Off-white. Odor Practically odorless.

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

range

Flash point Not available. Not available. **Evaporation rate** Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Not available.

Flammability limit - lower

(%)

Flammability limit - upper

Not available.

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Material name: Cephapirin Benzathine

USP SDS US

1102408 Version #: 04 Revision date: 03-08-2019 Issue date: 02-24-2003

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Slightly soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Cephalosporin.

Molecular formula (C17H17N3O6S2)2. C16H20N2

Molecular weight 1087.27

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

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

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.

Skin sensitization May cause an allergic skin reaction.

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 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

Studies in animals have not shown that cephalosporins cause adverse effects on the fetus.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - Knowledge about health hazard is incomplete.

repeated exposure

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

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

No data is available on the degradability of this product. Persistence and degradability

Bioaccumulative potential No data available. Mobility in soil 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

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the **Disposal instructions**

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 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

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

shipment.

Not applicable.

15. Regulatory information

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

One or more components are not listed on TSCA.

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

Standard, 29 CFR 1910.1200.

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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard

categories

Respiratory or skin sensitization

SARA 313 (TRI reporting)

Not regulated.

Material name: Cephapirin Benzathine

1102408 Version #: 04 Revision date: 03-08-2019 Issue date: 02-24-2003

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

Inventory name

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material US state regulations

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

New Zealand

Philippines

Country(s) or region

3 \(\)	•	3 (3)
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

Philippine Inventory of Chemicals and Chemical Substances (PICCS)

Taiwan Taiwan Chemical Substance Inventory (TCSI) United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

New Zealand Inventory

No

Yes

No

No

On inventory (yes/no)*

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

Issue date 02-24-2003 03-08-2019 **Revision date**

Version #

Disclaimer

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Material name: Cephapirin Benzathine

1102408 Version #: 04 Revision date: 03-08-2019 Issue date: 02-24-2003

^{*}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).