SAFETY DATA SHEET



1. Identification

Product identifier Cefprozil Related Compound D

Other means of identification

Catalog number 1097986 106447-44-3 **CAS** number **Synonyms** 7-PACA

(6R,7R)-7-Amino-8-oxo-3-[(Z)-prop-1-enyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid Chemical name

Recommended use For analytical laboratory use only.

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

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790 **United States**

Telephone Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 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

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

Label elements



Signal word

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

difficulties if inhaled.

Precautionary statement

Avoid breathing dust/fume/gas/mist/vapors/spray. Contaminated work clothing must not be Prevention

allowed out of the workplace. Wear 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.

Not available. Storage

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

USP SDS US 1097986 Version #: 03 Revision date: 05-25-2021 Issue date: 11-15-2011

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|------------------------------|--------------------------|-------------|-----|
| Cefprozil Related Compound D | 7-PACA | 106447-44-3 | 100 |

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Do not use mouth-to-mouth method if the substance is inhaled. If experiencing respiratory

symptoms: Call a poison center or doctor/physician.

Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. Take Skin contact

off contaminated clothing and wash before reuse.

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

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure Most important may cause physiological effects.

symptoms/effects, acute and

delayed

treatment needed

Indication of immediate medical attention and special

Provide general supportive measures and treat symptomatically.

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

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.

General fire hazards No 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.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, 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.

1097986 Version #: 03 Revision date: 05-25-2021 Issue date: 11-15-2011

Conditions for safe storage, including any incompatibilities

Store in tight container. 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

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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

Consider double gloves. 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 disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover 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

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS

are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance

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

Physical stateSolid.FormPowder.

Color White. Off-white.

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 pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Material name: Cefprozil Related Compound D

USP SDS US

Solubility (other) Aqueous base: Slightly.

DMSO: Sparingly (heated, sonicated)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. **Viscosity** Not available.

Other information

C10H12N2O3S Molecular formula

240.28 Molecular weight

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Material is stable under normal conditions. Chemical stability

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials None known.

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

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Respiratory sensitization

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. Knowledge about carcinogenicity is incomplete. Carcinogenicity

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.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Material name: Cefprozil Related Compound D

Further information Pharmaceutical related compound of unknown potency. It is not known if 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 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

Disposal instructionsDispose 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 in accordance with all applicable regulations.

Hazardous waste codeThe 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

Not applicable.

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

shipment.

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.

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.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

Classified hazard

Respiratory or skin sensitization

categories

1097986 Version #: 03 Revision date: 05-25-2021 Issue date: 11-15-2011

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

(SDWA)

Taiwan

Not regulated.

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

| 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) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |

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

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

11-15-2011 Issue date 05-25-2021 Revision date

Version # 03

Disclaimer USP materials are sold for analytical laboratory use only, and NOT for human consumption. The

information contained herein is applicable solely to the chemical substance when used for analytical laboratory use 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 materials 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.

No

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).