usp

SAFETY DATA SHEET

1. Identification

Product identifier Cefuroxime Sodium

Other means of identification

 Catalog number
 1098209

 CAS number
 56238-63-2

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

3-[[(aminocarbonyl)oxy]methyl]-7-[[2-furanyl(methoxyimino)acetyl]amino]-8-oxo-, monosodium salt

[6R-[6alpha,7beta(Z)]]-

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

Manufacturer

Company name U. S. Pharmacopeia
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

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 Serious eye damage/eye irritation Category 2B

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. Causes eye irritation. May cause allergy or asthma symptoms

or breathing difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. In case of

inadequate ventilation wear respiratory protection. Contaminated work clothing should not be

allowed out of the workplace. Wear protective gloves.

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

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. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Storage Not available.

Disposal

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

Hazard(s) not otherwise classified (HNOC)

This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be

hazardous.

Supplemental information

Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Cefuroxime Sodium		56238-63-2	100

4. First-aid measures

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

Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other

proper respiratory medical device. Call a physician if symptoms develop or persist.

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

off contaminated clothing and wash before reuse.

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if Eye contact

present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Pharmacologically active material. Occupational exposure may cause physiological effects.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important

symptoms/effects, acute and

delaved

Indication of immediate medical attention and special treatment needed

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

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

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. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

ına	ustr	ıaı	use

Material	Туре	Value	
Cefuroxime Sodium (CAS 56238-63-2)	STEL	100 micrograms/m3	

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

Eve/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.

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

Solid. Physical state **Form** Powder.

Color White. Light yellow. Odor Not available. **Odor threshold** Not available. Not available. рH

Melting point/freezing point 420.8 °F (216 °C) (decomposes)

Initial boiling point and boiling

range

Not available.

Not available. Flash point Not available. **Evaporation rate**

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

(%)

Flammability limit - upper

Flammability limit - lower

(%)

Not available.

Not available.

Explanive limit lewer (9/)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

or pressure Not available.

Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Benzene: Very slightly soluble.

Buffered solutions: Freely soluble. Chloroform: Very slightly soluble. Ethanol: Very slightly soluble. Ether: Very slightly soluble. Ethyl acetate: Very slightly soluble.

Methanol: Soluble.

Octanol: Very slightly soluble.

Partition coefficient (n-octanol/water)

-0.429

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical family Cephalosporin.

Dust explosion properties

Kst 141 bar.m/s

St class 1 Weak explosion.

Minimum ignition energy (MIE) - dust

energy (r

> 500 mJ

Molecular formula C16H15N4NaO8S Molecular weight 446.37 g/mol

pH in aqueous solution 6 - 8.5 Solution: 10%

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 avoidContact with incompatible materials. Avoid heat, sparks, open flames and other ignition sources.

Incompatible materials Oxidizing agents. Alkali metals.

Hazardous decomposition

products

NOx, SOx, Na. 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 Causes eye irritation.

Ingestion Knowledge about health hazard is incomplete.

Material name: Cefuroxime Sodium

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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

Product Species Test Results

Cefuroxime Sodium (CAS 56238-63-2)

Acute Dermal

LD50 Rabbit > 200 mg/kg

Inhalation

LC50 Rat > 1180 mg/m3, 4 hours

Oral

LD50 Mouse > 10 g/kg
Rat > 10 g/kg

Skin corrosion/irritation

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

Serious eye damage/eye

e/eye Causes eye irritation.

irritation

Local effects

Eye irritancy test Result: Slight irritation. Species: Rabbit Skin irritancy test Result: Slight irritation. Species: Rabbit

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.

Guinea pig test Result: Negative.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Forward mutation test in mouse lymphoma cells

Result: Negative.

In vitro chromosomal aberration tests

Result: Positive.

In vivo mouse bone marrow micronucleus test

Result: Negative.

Reverse mutation tests in S. typhimurium and E. coli

Result: Negative.

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

Epidemiological studies have not shown an association between therapeutic use of this material

during pregnancy and an increased incidence of birth defects.

Reproductivity

400 mg/kg/day Reproductivity and development study Result: No impaired fertility or harm to the fetus noted.

Species: Rabbit

6400 mg/kg/day Reproductivity and development study Result: No impaired fertility or harm to the fetus noted.

Species: Mouse

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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**

Pharmacologically active material. Occupational exposure may cause physiological effects. **Further information**

12. Ecological information

Ecotoxicity

Product		Species	Test Results	
Cefuroxime Sodium (CAS 56238-63-2)			
Acute				
Other	IC50	Pseudokirchnerella subcapitata	> 91 mg/l, 72 hours	
Aquatic				
Acute				
Crustacea	EC50	Daphnia magna	> 876 mg/l, 48 hours	
Fish	LC50	Rainbow Trout	> 105 mg/l, 96 hours	

Persistence and degradability

Not readily biodegradable.

Expected to be inherently biodegradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

-0.429

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).

Since emptied containers may retain product residue, follow label warnings even after container is Contaminated packaging

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 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

Yes

chemical

Classified hazard Serious eye damage or eye irritation categories Respiratory or skin sensitization

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)	Yes
Canada	Domestic Substances List (DSL)	Yes
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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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
 12-27-2007

 Revision date
 10-07-2020

Version # 03

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Material name: Cefuroxime Sodium

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).

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