

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Ceftriaxone for Injection USP**
250 mg, 1 g, 2 g and 10 g ceftriaxone per vial (as Ceftriaxone Sodium)

Recommended use : Dosage form
Therapeutic category: Antibiotic

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

Supplier	Canada Apotex Inc. 150 Signet Drive Toronto, Ontario M9L 1T9 416-749-9300	U.S. Apotex Corp. 2400 N. Commerce Parkway Suite 400 Weston, FLA 33326 Telephone: (954)384-8007 Toll Free: 1-800-706-5575
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Emergency phone : United States/Canada (Chemtrec) 1-800-424-9300 or
+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Ceftriaxone sodium	104376-79-6	100
Specific chemical identity and/or percentage of composition has been withheld as a trade secret.		

Chemical name : 5-Thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid, 7-(((2-amino-4-thiazolyl)(methoxyimino)acetyl)amino)-8-oxo-3-((1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-1,2,4-triazin-3-yl)thio)methyl)-, disodium salt, (6R-(6- α ,7- β (Z))) hydrate

Synonyms : Brand Name: Rocephin

Chemical family : Cephalosporin

Molecular weight : 661.6 g/mole

Chemical formula : $C_{18}H_{16}N_8Na_2O_7S_3 \cdot 3.5 H_2O$

Section 4. First Aid Measures

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : Flush with copious amounts of water. Seek medical attention if irritation persist.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

Section 5. Fire Fighting Measures

- Specific hazard arising from the chemical** : During fire, gases hazardous to health may be formed.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

- Methods and materials for containment and cleaning up** : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, refer to section 8 of the SDS.

Section 7. Handling and Storage

- Precautions for safe handling** : Avoid breathing dust.
- Conditions for safe storage** : Store powder at 20°-25°C (68°-77°F). Protect from light.

Section 8. Exposure Controls/Personal Protection

- Engineering Controls** : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, appropriate PPE may be required that includes NIOSH approved respirators.

EYE/FACE PROTECTION: Wear approved safety eyewear if eye contact is possible.

SKIN PROTECTION: Where there is a risk of contact when handling, wear suitable skin protection (e.g., gloves, lab coat/uniform) having resistance to the product.

HYGIENE MEASURES: In the event clothing becomes contaminated, remove promptly. Launder before use. When handlings, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : TWA: Industry: 0.02 mg/m³; STEL 0.06 mg/m³ (USP)

Section 9. Physical and Chemical Properties

Physical state and appearance : Sterile crystalline powder

pH : Not available.

Odor : Not available.

Melting point/Freezing point : >155°C (311°F) (decomposes)

Odor threshold : Not available.

Boiling point : Not available.

Conditions of instability : No additional remark.

Volatility : Not available.

Decomposition temperature : Not available.

Specific gravity : Not available.

Partition Coefficient: : Not available.

Evaporation rate : Not available.

Viscosity : Not available.

Vapor density : Not available.

Flash points : Not applicable.

Relative density : Not available.

Flammable limits : Not available.

Vapor pressure : Not available.

Autoignition temperature : Not available.

Flammability : Emits toxic fumes under fire conditions.

Solubility : Freely soluble in water.
Sparingly soluble in methanol; very slightly soluble in alcohol

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable.

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : Not available.

Incompatible materials/ Conditions to avoid : Avoid exposure to heat and moisture.

Section 11. Toxicological Information

Information on the likely routes of exposure : Ingestion. Inhalation.

Toxicity data : RTECS#: XI0368800
LD50: >10 gm/kg (oral-rat)
LD50: >10 gm/kg (oral-mouse)

Delayed and immediate effects and also chronic effects from short and long term exposure : Possible hypersensitization, superinfections, antibiotic-associated pseudomembranous colitis, and pseudolithiasis.
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA.
Reproductive Toxicity: Ceftriaxone produced no impairment of fertility when given intravenously to rats at daily doses up to 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 gm/day.
Teratogenicity: Pregnancy Category B. Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryotoxicity, fetotoxicity or teratogenicity. In primates, no embryotoxicity or teratogenicity was demonstrated at a dose approximately 3 times the human dose. There are, however, no adequate and well- controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Mutagenicity: Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured in vitro with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material; active alcoholism or recent alcohol ingestion; allergies; history of bleeding disorders; concurrent kidney and liver function impairment; gallbladder disease; and gastrointestinal disease, especially ulcerative colitis, regional enteritis, or antibiotic-associated colitis. Persons allergic to one cephalosporin or cephamycin or to penicillins, penicillin derivatives, or penicillamine may be allergic to this material also.

Symptoms related to the physical, chemical and toxicological characteristics : Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
Adverse effects of cephalosporins may include 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; skin itching, rash, or redness; hives; abdominal or stomach pain or cramps; nausea or vomiting; diarrhea; headache; indigestion; flatulence; unusual tiredness or weakness; loss of appetite; dizziness; and vaginal itching, infection, or discharge. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Overdose effects of cephalosporins may include the adverse effects listed above and seizures.

Section 12. Ecological Information

Ecotoxicity : This material is strongly toxic for microorganisms and barely toxic for fish, planktonic crustaceans, and algae.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label	Additional information (e.g., special precautions, environmental hazards, transport in bulk)
TDG- road Canada/U.S.			Not regulated.			
ICAO-Air			Not regulated.			
ADR			Not regulated.			
IMDG Class			Not regulated.			

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS
Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
RxList Monographs
U.S. Pharmacopeia

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Notice to Reader

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