APOTEX
ADVANCING GENERICS

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Cefazolin for Injection USP**

Recommended use : Dosage form
Therapeutic category: Antibacterial.

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 :

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Apotex Inc.
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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

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)
Cefazolin sodium	27164-46-1	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, 3-[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[[1H-tetrazol-1-yl)acetyl]amino]-(6R-trans)

Synonyms : Brand name: Ancef

Chemical family : Cephalosporin

Molecular weight : 476.52 g/mole

Chemical formula : $C_{14}H_{13}N_8O_4S_3.Na$

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 inhalation, skin and eye contact.

Conditions for safe storage : Before reconstitution protect from light and store 20°C to 25°C (68° to 77°F).

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 : PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. For spills, refer to section 6. If the physical state of the finished product is altered by crushing, grinding or breakage, 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 handling, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : Sterile crystalline powder.

pH :	Between 4.0 and 6.0 (10% w/v aq. solution)	**Odor** :	Not available.
Melting point/ Freezing point :	Not available.	**Odor threshold** :	Not available.
Boiling point :	Not available.	**Conditions of instability** :	No additional remark.
Volatility :	Not available.	**Decompositon 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, very slightly soluble in alcohol.

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable. Very hygroscopic (absorbs moisture from the air).

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : When heated to decomposition material emits toxic fumes.

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

Section 11. Toxicological Information

Information on the likely routes of exposure : Skin contact. Eye contact

Toxicity data : RTECS#: XI0390000
TDLo: 14 mg/kg/Day (intramuscular-human)
LD50: >11 gm/kg (oral-rat)
LD50:> 11gm/kg (oral-mouse)
LD50: 4 gm/kg (intramuscular-mouse)
Sensitization data: Hypersensitivity reactions have been reported with therapeutic use of cephalosporins. Cases of anaphylaxis have been reported with the use of cefazolin.

Delayed and immediate effects and also chronic effects from short and long term exposure : Possible hypersensitization, antibiotic-associated pseudomembranous colitis, and superinfections.

Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA.

Reproductive and Developmental Effects: Pregnancy Category B. In rats, doses up to 2000 mg/kg were not associated with gestational or reproductive toxicity. A slight reduction in fetal weight was found in rats given up to 800 mg/kg of cefazolin intravenously on day 7 to 17 of gestation. No developmental effect was observed in rabbits and mice after cefazolin in daily doses of 240 m/kg and 2400 mg/kg respectively.

Mutagenicity: Cefazolin was shown to be non-mutagenic in the Ames test, mouse lymphoma test, and the mouse micronucleus test.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material; active alcoholism; history of bleeding disorders; kidney function impairment; and gastrointestinal disease, especially ulcerative colitis, regional enteritis, or antibiotic-associated colitis.
Individuals sensitive to penicillins, penicillin derivatives, penicillamine, other cephalosporins, or cephamycin may be sensitive to this material also.

Symptoms related to the physical, chemical and toxicological characteristics : Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
Adverse effects for 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 cramps, tenderness, or pain; nausea or vomiting; watery, bloody, or severe 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.

Section 12. Ecological Information

Ecotoxicity : Not available.

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
PDR Electronic Library
Apotex Product Monograph
U.S. Pharmacopeia

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Notice to Reader

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