



MATERIAL SAFETY DATA SHEET

Product Name: Cefazolin for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone Hospira, Inc. CHEMTREC: 800-424-9300
224 212-2055

Product Name Cefazolin for Injection

Synonyms Cefazolin Sodium; 3-[[5-methyl-1,3,4-thiadiazol-2-yl]thio]-methyl]-8-oxo-7-[2-(1H-tetrazol-1-yl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, sodium salt.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Cefazoline Sodium
Chemical Formula $C_{14}H_{13}N_8O_4S_3 \cdot Na$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Cefazolin Sodium	100	27164-46-1	XI0390000

3. HAZARD INFORMATION / CLASSIFICATION

Emergency Overview Cefazolin for Injection contains cefazolin sodium, a cephalosporin antibacterial agent used to treat infections due to susceptible organisms. No adverse effects are anticipated from normal handling of the intact container. Following an accidental exposure, the powdered cefazolin sodium may produce skin, eye, or respiratory irritation. The reconstituted product is not anticipated to be irritating. Persons known to be allergic to penicillins or other cephalosporins should take precautions when handling this material. Following an accidental over-exposure, possible target organs may include the gastrointestinal system, liver, kidneys, blood, and skin.

Occupational Exposure Potential Minimal occupational exposure is anticipated from normal handling of the intact container. Avoid liquid aerosol generation and inadvertent skin contact.

Signs and Symptoms No signs or symptoms of exposure are anticipated from normal handling of the intact container. Based on clinical use of this product in patients, following an accidental occupational exposure, possible adverse effects may include gastrointestinal upset (nausea, vomiting, stomach cramps, loss of appetite), headache, dizziness, elevated liver enzymes, elevated kidney enzyme levels, and altered hematological parameters (anemia, neutropenia, thrombocytopenia). Persons allergic to penicillins or other cephalosporin antibiotics may experience allergic reactions including fever, rash, itching, difficulty breathing, or anaphylaxis.

Medical Conditions Aggravated by Exposure Pre-existing allergy to cefazolin sodium, penicillins, or other cephalosporin antibiotics. Pre-existing gastrointestinal system, liver, kidney, skin, or hematological ailments.

4. FIRST AID MEASURES

Eye Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	Non-flammable
Fire & Explosion Hazard	None anticipated for this product. None anticipated after reconstitution with water.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special requirements are needed for single units or packages. For larger amounts, self-contained breathing apparatus and protective equipment and clothing are recommended to minimize contact with respiratory tract, skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	<p>If a container breaks, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.</p> <p>If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.</p>
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7. HANDLING AND STORAGE

Handling	No special control measures are required during the normal use of this product. During dispensing, avoid excessive aerosolization of the reconstituted product during dilution or transfers.
Storage	No special storage required for hazard control. Before reconstitution, to maintain the integrity of the product, store at or below room temperature (20° to 25°C or 68 to 77°F) and protect from light.
Special Precautions	None anticipated during the normal use of this product. Persons with known allergies to penicillins or other cephalosporins should consult a health or safety professional prior to handling this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Cefazolin Sodium	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 EEL: Employee Exposure Limit.
 TWA: 8 hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

- Respiratory Protection** Respiratory protection is not needed during the normal use of this product. However, persons with known allergies to penicillins or other cephalosporins should consult their site health or safety professional regarding appropriate respiratory protection prior to handling this material.

- Skin Protection** If contact with unprotected skin is possible, the use of gloves is recommended. Persons with known allergies to penicillins or other cephalosporins should consult their site health or safety professional regarding appropriate selection of gloves prior to handling this material.

- Eye Protection** Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

- Engineering Controls** Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

- Appearance/Physical State** White or almost white hygroscopic powder

- Odor** Practically odorless

- Melting Point** 198°C– 200°C

- Freezing Point** NA

- Vapor Pressure** NA

- Vapor Density (Air =1)** NA

- Evaporation Rate** NA

- Bulk Density** NA

- Specific Gravity** NA

- Solubility** Freely soluble in water, 0.9% sodium chloride, and in glucose solutions

- pH** 4.6 – 6.0 for a 10% solution

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under recommended storage conditions and use.
Incompatibilities	Not determined. Cefazolin sodium is reported to be clinically incompatible with aminoglycosides.
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), sodium oxides (Na ₂ O), and sulfur oxides (SO _x).
Hazardous Polymerization	Not determined. Not anticipated to occur with this material.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Cefazolin Sodium	100	LD50	> 11,000	mg/kg	Rat
Cefazolin Sodium	100	LD50	> 11,000	mg/kg	Mouse

LD50 is the dosage producing 50% mortality.
 LC50 is the air concentration producing 50% mortality.

Acute Toxicity – Intravenous:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Cefazolin Sodium	100	LD50	2760	mg/kg	Rat
	100	LD50	3900	mg/kg	Mouse
	100	LD50	2200	mg/kg	Dog
	100	LD50	2500	mg/kg	Rabbit

LD50 is the dosage producing 50% mortality.

Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of intact containers. This material is reported to be non-irritating in a skin irritation study in rabbits.
Ocular Irritation/Corrosion	None anticipated from normal handling of intact containers. This material is reported to be slightly irritating in an eye irritation study in rabbits.
Dermal or Respiratory Sensitization	None anticipated from normal handling of intact containers. As a class, cephalosporin antibiotics are sensitizers in studies in animals. Allergic reactions have been reported during the clinical use of this product.
Reproductive Effects	Reproduction studies conducted in rats, mice, and rabbits at doses up to 25 times the human dose have revealed no evidence of impaired fertility or harm to the fetus.
Mutagenicity	Not determined.
Carcinogenicity	Not determined.
Target Organ Effects	Based on clinical use, possible target organs include the gastrointestinal system, liver, kidneys, blood, and skin.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity	Not determined.
Biodegradation	Not determined.
General Notes	None

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	If discarded as produced, this material is not a RCRA “listed” or “characteristic” hazardous waste. However, uses resulting in a chemical or physical change of the product, or contamination of the product with other materials may subject it to regulation as a hazardous waste. All waste materials must be properly characterized. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS: Not regulated

Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

ICAO/IATA STATUS Not regulated

Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

IMDG STATUS Not regulated

Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Exempt
CERCLA Status	Not listed
SARA 302 Status	Not listed
SARA 313 Status	Not listed
RCRA Status	Not a hazardous waste
PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

U.S. OSHA Classification	Possible sensitizer Target Organ Toxin
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GHS Classification

**Hazard Category
Symbol**

Category 1



Category 1



Category 2



**Signal Word
Hazard Statement**

Warning
May cause an allergic skin reaction.

Danger
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

Warning
May cause damage to the gastrointestinal system, liver, kidneys, blood, and skin through prolonged or repeated exposure.

GHS Precautionary Statements:

Prevention:

Avoid breathing dust or vapors. In case of inadequate ventilation wear respiratory protection. Wear protective gloves. Contaminated work clothing should not be allowed out of the workplace.

Response:

IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or a doctor.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical advice. Wash contaminated clothing before reuse.

EU Classification and Labeling

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance cefazolin sodium.

Classification(s): Sensitizer

Symbol:



Indication of Danger: Xn

Risk Phrases:
R42 – May cause sensitization by inhalation
R43 – May cause sensitization by skin contact

Safety Phrases:
S22: Do not breathe dust
S24: Avoid contact with the skin
S37: Wear suitable gloves

Combination Safety Phrases: Not determined.

16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD ₅₀	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Global Occupational Toxicology
Date Prepared: May 15, 2007
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Disclaimer:

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