



SAFETY DATA SHEET

Revision date: 09-Mar-2015

Version: 4.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Cefobid (sterile cefoperazone, USP)

Trade Name: CEFOBID®; MAGNAMYCIN
Synonyms: Cefoperzone sodium for injection
Chemical Family: Cephalosporin antibiotic

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Harmful
Irritant

EU Risk Phrases:

R42 - May cause sensitization by inhalation.
R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Danger
Hazard Statements: H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
May form combustible dust concentrations in air

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Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory protection
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental first aid instructions on this label)
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Cefoperazone sodium	62893-20-3	263-751-5	Xn;R42 Xi;R43	Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	100

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Cefoperazone sodium

Pfizer OEL TWA-8 Hr: 1000µg/m³, Sensitizer

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	C ₂₅ H ₂₆ N ₉ NaO ₈ S ₂	Molecular Weight:	667.65

Solvent Solubility:	No data available
Water Solubility:	No data available
Solubility:	Soluble: Water
pH:	4.5 - 6.5 (25% aqueous solution)
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	

Cefoperazone sodium

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

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Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term: Inhalation of significant quantities of this substance could result in the health effects described in 'Known clinical effects'. Ingestion of this material can cause effects similar to those seen in clinical use including cholinergic crisis, characterized by severe nausea, vomiting, salivation, sweating, slow heart rate, low blood pressure, muscle weakness, respiratory depression.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Concomitant administration of aminoglycosides and cephalosporins has caused nephrotoxicity. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

Acute Toxicity: (Species, Route, End Point, Dose)

Cefoperazone sodium

Rat Oral LD50 > 15 g/kg
Mouse Oral LD50 > 12g/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Skin Irritation / Sensitization Hypersensitivity reactions, including cross reactions (with penicillins) and anaphylaxis, are common among the cephalosporins. No data available

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Cefoperazone sodium

3 Month(s)	Dog	Intravenous	200 mg/kg/day	NOAEL	Thymus, Blood
3 Month(s)	Dog	Intramuscular	125 mg/kg/day	NOAEL	Thymus, Blood

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Cefoperazone sodium

Embryo / Fetal Development	Monkey	Intravenous	50 mg/kg/day	LOEL	Maternal toxicity, Not teratogenic
Reproductive & Fertility-Males	Rat	Subcutaneous	1000 mg/kg/day	LOAEL	Fertility
2 Generation Reproductive Toxicity	Rat	No route specified	500 mg/kg/day	NOAEL	No effects at maximum dose

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11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development Rat Subcutaneous 1000 mg/kg/day NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Cefoperazone sodium

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Dominant Lethal Assay	Mouse	Negative
Cytogenetics Bone Marrow		Negative

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B



Cefoperazone sodium

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Australia (AICS):

Present

EU EINECS/ELINCS List

263-751-5

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xi - Irritant

Xn - Harmful

R42 - May cause sensitization by inhalation.

R43 - May cause sensitization by skin contact.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage.

Revision date: 09-Mar-2015

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet