

### 1 IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

**Product Name:** Cefoxitin for Injection, USP

**Distributed By:** WG Critical Care, LLC  
 120 Route 17 North  
 Suite 115  
 Paramus, NJ 07652 USA

**Customer Service Phone Number:** 1-888-493-0861  
**Emergency Phone Number:** 1-866-562-4708 (ProPharma)

**Product Use:** Prescription Drug  
**Product Type:** Anti-infective  
**Container Information:** Vial

### 2 HAZARDS IDENTIFICATION

**Classification of Substance or Mixture:** Skin Sens. 1;H317  
 May cause an allergic skin reaction.

**Label Elements:** Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.  
 H317 May cause an allergic skin reaction.  
 [Prevention]:  
 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 / eye protection / face protection.



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### 3 COMPOSITION / INFORMATION ON INGREDIENTS

#### SUBSTANCE OR MIXTURE:

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Cefoxitin Sodium	100	33564-30-6

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

Chemical Name: (1) 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[[(aminocarbonyl)oxy)methyl]-7-methoxy-8-oxo-7-[(2-thienylacetyl)amino]-, sodium salt, (6R-cis)-; (2) Sodium (6R,7S)-3-(hydroxymethyl)-7-methoxy-8-oxo-7-[2-(2-thienyl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate carbamate (ester)

Molecular Formula: C16H16N3NaO7S2

UNII Code: UNII-Q68050H03T

CAS Number: CAS-33564-30-6

### 4 FIRST AID MEASURES

#### Description of first aid measures

<b>GENERAL:</b>	Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.
<b>INHALATION:</b>	Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.
<b>EYES:</b>	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
<b>SKIN:</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
<b>INGESTION:</b>	If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

#### OVERVIEW:

<b>Indication of any immediate medical attention and special treatment needed:</b>	See patient package insert in shipping carton for complete information.
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### 5 FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use foam or an all-purpose dry chemical to extinguish.
<b>Special hazards arising from the substance or mixture:</b>	Hazardous decomposition: When heated to decomposition material emits toxic fumes of NO <sub>x</sub> , SO <sub>x</sub> . Emits toxic fumes under fire conditions. Avoid breathing dust, fume, gas, mist, vapor, spray.

### 6 ACCIDENTAL RELEASE MEASURE

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear positive pressure self-contained breathing apparatus and full turnout gear.
<b>Environmental precautions</b>	Prevent entry to sewers and public waters.
<b>Methods and material for containment and cleaning up</b>	<p>Spill: Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.</p> <p>Release to Air: Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.</p> <p>Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.</p>

### 7 HANDLING AND STORAGE

<b>Precautions for safe handling</b>	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. This material has not been tested for its dust explosion properties. However, like most organic dusts, it is expected to explode when ignited as a dust cloud. Care should be taken to avoid dispersion as a dust cloud.
<b>Conditions for safe storage, including any incompatibilities</b>	Store the final dosage form at 20 to 25 deg C. Avoid exposure to temperatures above 50 deg C.
<b>Specific end use(s)</b>	Usual Adult Dose: Cefoxitin for Injection is administered by intravenous infusion; typical doses range from 1 to 2 grams (Cefoxitin) every 4, 6 or 8 hours (must be prescribed by physicians).

### 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

#### CONTROL PARAMETERS:

<u>CAS No.</u>	<u>Ingredient</u>	<u>Value</u>	<u>Control Parameters</u>
33564-30-6	Sodium (6R-cis)-3- [(carbamoyloxy)methyl]- 7-methoxy-8-oxo-7-(2- thienylacetamido)-5- thia-1- azabicyclo[4.2.0]oct-2- ene-2-ca	No limit No limit No limit	ACGIH Ceiling (mg/m <sup>3</sup> ) NIOSH REL (ceiling) (mg/m <sup>3</sup> ) OSHA PEL (TWA) (mg/m <sup>3</sup> )
35607-66-0	Cefoxitin	No limit No limit No limit	ACGIH Ceiling (mg/m <sup>3</sup> ) NIOSH REL (ceiling) (mg/m <sup>3</sup> ) OSHA PEL (TWA) (mg/m <sup>3</sup> )

#### Carcinogen Data

<u>CAS No.</u>	<u>Ingredient</u>	<u>Source</u>	<u>Control Parameters</u>
33564-30-6	Sodium (6R-cis)-3- [(carbamoyloxy)methyl]- 7-methoxy-8-oxo-7-(2- thienylacetamido)-5- thia-1- azabicyclo[4.2.0]oct-2- ene-2-ca	OSHA NTP IARC	Select Carcinogen: No Known: No; Suspected: No Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
35607-66-0	Cefoxitin	OSHA NTP IARC	Select Carcinogen: No Known: No; Suspected: No Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

#### EXPOSURE CONTROLS

<b>Respiratory:</b>	With satisfactory ventilation, respiratory protection is usually not required.
<b>Eyes:</b>	Chemical safety goggles.
<b>Skin:</b>	Disposable latex gloves recommended. Disposable garments if direct skin contact is anticipated.
<b>Engineering Controls:</b>	General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.
<b>Other Work Practices:</b>	No special ventilation required. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

### 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE:</b>	Crystalline Powder	<b>APPEARANCE:</b>	White to Off White Crystalline Powder
<b>UPPER FLAMMABILITY LIMIT:</b>	No data available	<b>LOWER FLAMMABILITY LIMIT:</b>	No data available
<b>EXPLOSIVE LIMITS:</b>	No data available	<b>ODOR:</b>	Slight characteristic odor
<b>VAPOR PRESSURE:</b>	No data available	<b>ODOR THRESHOLD:</b>	N/A
<b>VAPOR DENSITY:</b>	Greater than one	<b>pH:</b>	4.2 – 7.0
<b>RELATIVE DENSITY:</b>	Approximate to water	<b>MELTING POINT:</b>	150 deg C
<b>FREEZING POINT:</b>	No data available	<b>SOLUBILITY:</b>	Soluble in water
<b>INITIAL BOILING POINT:</b>	No data available	<b>BOILING RANGE:</b>	No data available
<b>FLASH POINT:</b>	Not flammable	<b>EVAPORATION RATE:</b>	Similar to water
<b>FLAMMABILITY:</b>	Not flammable	<b>PARTITION COEFFICIENT (N-OCTANOL / WATER)</b>	No data available
<b>AUTO-IGNITION TEMPERATURE:</b>	No data available	<b>DECOMPOSITION TEMPERATURE:</b>	No data available
<b>VISCOSITY:</b>	No data available		

### 10 STABILITY AND REACTIVITY

<b>Reactivity:</b>	No known reactivity hazard under normal conditions.
<b>Chemical Stability</b>	Stable under normal circumstances.
<b>Possibility of Hazardous reactions:</b>	Hazardous polymerization will not occur.
<b>Conditions to avoid:</b>	Avoid direct sunlight and conditions that might generate heat and dispersion.
<b>Incompatible Materials:</b>	Incompatible with oxidizing agents.
<b>Hazardous decomposition products:</b>	When heated to decomposition material emits toxic fumes of NO <sub>x</sub> , SO <sub>x</sub> . Emits toxic fumes under fire conditions.

### 11 TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY

COMPONENT	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-ca - (33564-30-6)	No data available	No data available	No data available	No data available	No data available
Cefoxitin - (35607-66-0)	Rat – 10g/kg	No data available	No data available	No data available	No data available

Note: As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

#### Signs & Symptoms of Exposure & Overexposure:

This product is intended for therapeutic use only when prescribed by a physician.

Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses include: allergic reactions, hypotension, gastrointestinal neuromuscular, renal, and hepatic abnormalities.

Occupational exposure has not been fully investigated.

#### Medical Conditions Aggravated by Accidental Exposure:

Individuals with hypersensitivity to cefoxitin and to the cephalosporin and penicillin group of antibiotics.

**IMMEDIATE EFFECTS:** Eye, skin, and respiratory irritation may occur. Exposure may cause allergic reactions in certain individuals and cross-allergenicity with penicillin allergic individuals.

**DELAYED EFFECTS:** Hypersensitivity reactions ranging from mild to life-threatening may occur.

<u>Classification</u>	<u>Category</u>	<u>Hazard Description</u>
Acute toxicity (oral)		Not Applicable
Acute toxicity (dermal)		Not Applicable
Acute toxicity (inhalation)		Not Applicable
Skin corrosion/irritation		Not Applicable
Serious eye damage/irritation		Not Applicable
Respiratory sensitization		Not Applicable
Skin sensitization	1	May cause an allergic skin reaction.
Germ cell mutagenicity		Not Applicable
Carcinogenicity		Not Applicable
Reproductive toxicity		Not Applicable
STOT-single exposure		Not Applicable
STOT-repeated exposure		Not Applicable
Aspiration hazard		Not Applicable

## 12 ECOLOGICAL INFORMATION

### Toxicity

Aquatic Ecotoxicity

<b>Ingredient</b>	<b>96 hr LC50 fish, mg/l</b>	<b>48 hr EC50 crustacea, mg/l</b>	<b>ErC50 algae, mg/l</b>
Sodium (6R-cis)-3-[(carbamoyloxy)methyl]-7-methoxy-8-oxo-7-(2-thienylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-ca - (33564-30-6)	Not Available	Not Available	Not Available
Cefoxitin - (35607-66-0)	Not Available	Not Available	Not Available

Persistence and degradability - There is no data available on the preparation itself.

Bioaccumulative potential - Not Measured

Mobility in soil - No data available

Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals

Other adverse effects - No data available

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### 13 DISPOSAL CONSIDERATIONS

<b>Waste treatment methods</b>	Dispose of waste in accordance with federal and state regulations. Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
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<b>Contaminated Packaging</b>	
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### 14 TRANSPORT INFORMATION

**REGULATORY ORGANIZATIONS:**

**DOT:** Not Regulated

**ICAO / IATA:** Not Regulated

**IMO:** Not Regulated

### 15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

**US Regulations**

TSCA – No

CERCLA - No

SARA 302 – No

SARA 311/312 - No

SARA 313 – No

OSHA Substance Specific - No

EINECS Number: 251-574-6

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# Safety Data Sheet (SDS)

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### 16 OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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