

1 PRODUCT AND COMPANY INFORMATION

Distributed By:	WG Critical Care, LLC. 120 Route 17 North Suite 115 Paramus, NJ 07652 USA
Product Name:	CEFAZOLIN FOR INJECTION, USP
Primary Component/ Active Ingredient:	Cefazolin Sodium
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]-, monosodium salt (6R- <i>trans</i>)
Molecular Formula:	C ₁₄ H ₁₃ N ₈ O ₄ S ₃ .Na
UNII Code:	P380M0454Z
CAS Number:	27164-46-1
Chemical Family:	Cephalosporin Antibiotic
Product Use:	Antibacterial
Product Type:	Prescription Pharmaceutical
Container Information:	Vial
Customer Service Phone Number:	+1-888-493-0861
Emergency Phone Number:	+1-866-562-4708 (ProPharma)

2 HAZARDS IDENTIFICATION

Classification of Substance or Mixture:	RESPIRATORY SENSITIZATION - Category 1 SKIN SENSITIZATION - Category 1
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GHS Label Elements:

Signal word: DANGER



Hazard Statements: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317 - May cause an allergic skin reaction

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Precautionary Statements: Prevention: P280 - Wear protective gloves. P284 - Wear respiratory protection. P261 - Avoid breathing dust. P272 (OSHA) - Contaminated work clothing must not be allowed out of the workplace

Response: P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or physician. P302 + P352 + P363 - IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. P333 + P313 - If skin irritation or rash occurs: Get medical attention.

Disposal: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations

Hazard not otherwise classified: Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

3 COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Cefazolin for Injection	60-100	27164-46-1

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.

4 FIRST AID MEASURES

Description of first aid measures

GENERAL:

INHALATION: If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

EYES: 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: Remove contaminated clothing, wash skin with water and soap for 15 minutes. Seek medical attention if irritation or signs of exposure are noted.

INGESTION: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.

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5 FIRE FIGHTING MEASURES

Extinguishing Media:	Water spray, dry chemical, or foam as appropriate. Carbon dioxide extinguishers may be ineffective.
Special hazards arising from the substance or mixture:	When heated to decomposition it emits very toxic fumes of NO, Na ₂ O and SO.
Advice for Fire-Fighters:	Wear suitable protective equipment Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials. No unusual fire or explosion hazards noted

6 ACCIDENTAL RELEASE MEASURE

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground
Methods and material for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination

7 HANDLING AND STORAGE

Precautions for safe handling	No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes. Do not breathe dust. Minimize dust generation and accumulation.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed. Before reconstitution, store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Protect from light. See product label for additional information.
Specific end use(s)	See prescribing information.

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8 EXPOSURE CONTROLS / PERSONAL PROTECTION

CONTROL PARAMETERS:

<u>CAS No.</u>	<u>Ingredient</u>
27164-46-1	Cefazolin Sodium

EXPOSURE CONTROLS

Respiratory:	Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator
Eyes:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles
Skin:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product
Engineering Controls:	Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. In some cases, dust collection, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
Other Work Practices:	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

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9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Solid. Lyophilized Powder	APPEARANCE:	White / Off White
UPPER FLAMMABILITY LIMIT:	No data available	LOWER FLAMMABILITY LIMIT:	No data available
EXPLOSIVE LIMITS:	No data available	ODOR:	No Odor
VAPOR PRESSURE:	No data available	ODOR THRESHOLD:	No data available
VAPOR DENSITY:	No data available	pH:	4.5-6.0
RELATIVE DENSITY:	No data available	MELTING POINT:	198-200 deg C
FREEZING POINT:	No data available	SOLUBILITY:	Soluble in water, 0.9% sodium chloride, and in glucose solutions
INITIAL BOILING POINT:	No data available	BOILING RANGE:	No data available
FLASH POINT:	No data available	EVAPORATION RATE:	Approx. to water
FLAMMABILITY:	No data available	PARTITION COEFFICIENT (N-OCTANOL / WATER)	No data available
AUTO-IGNITION TEMPERATURE:	No data available	DECOMPOSITION TEMPERATURE:	No data available
VISCOSITY:	No data available		

10 STABILITY AND REACTIVITY

Reactivity:	No known reactivity hazard under normal conditions.
Chemical Stability	Stable under normal circumstances. Store in a cool and ventilated place at the temperature of 25°C ± 2C°. Avoid exposure to heat sources also localized.
Possibility of Hazardous reactions:	No data available.
Conditions to avoid:	No conditions producing hazardous situations known.
Incompatible Materials:	Strong oxidizing agents.

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Hazardous decomposition products:

Not determined. During thermal decomposition, it may generate toxic fumes of carbon oxides, nitrogen oxides, sodium oxides and sulfur oxides.

11 TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Cefazolin Sodium	LD ₅₀	IV	Rat	2760mg/kg

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.

Hazardous Chemical Listings

NTP: Not listed IARC: Not listed OSHA: Not listed NIOSH: Not listed

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact May cause an allergic skin reaction.

Eye contact Knowledge about health hazard is incomplete.

Ingestion Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and toxicological characteristics

Cephalosporins: Gastrointestinal disturbances. Respiratory difficulties. Sore throat. Vaginal itching. White patches in mouth.

12 ECOLOGICAL INFORMATION

Toxicity

Product/ingredient name	Result	Species	Exposure
Sodium (6R-trans)-3-[[[5-methyl-1,3,4-thiadiazol-2-yl]thio]methyl]-8-oxo-7-(1H-tetrazol-1-ylacetamido)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate	Acute EC50 >1000 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata	72 hours
	Chronic NOEC >1000 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata	72 hours

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Persistence and degradability

There is no data available.

Bioaccumulative potential There is no data available.

Mobility in soil

Soil/water partition coefficient (KOC)

Not available.

Other adverse effects : No known significant effects or critical hazards.

13 DISPOSAL CONSIDERATIONS

Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers

14 TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

IMO: Not Regulated

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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 313 – No

OSHA Substance Specific - No

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.

Revision History:

Version 3.0 Updated to GHS format.

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