

1 IDENTIFICATION

Product Identifier(s):

Product Name: Meropenem for Injection, USP
Chemical Name: (1) 1-Azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid, 3-[[5-[(dimethylamino)carbonyl]-3-pyrrolidinyl]thio]-6-(1-hydroxyethyl)-4-methyl-7-oxo-, trihydrate, [4R-[3(3S*,5S*),4a,5b,6b(R*)]]-; (2) (4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid, trihydrate.
Chemical Family: Beta-lactam

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

Recommended Use: Antibacterial
Uses Advised Against: This is a pharmaceutical product designed to be administered by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Product Type: 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
	EYE IRRITATION	Category 2
	ACUTE AQUATIC TOXICITY	Category 1
	CHRONIC AQUATIC TOXICITY	Category 1

Label Elements:

Signal Word: DANGER		WARNING	
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Hazard Statements:

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements:

Prevention:	P261	Avoid breathing dust.
	P264 + P265	Wash hands thoroughly after handling. Do not touch eyes.
Response:	P273	Avoid release to the environment.
	P280	Wear protective gloves.
	P284	Wear respiratory protection.
	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 information on this label).
	P362+P364	Take off contaminated clothing and wash it before reuse.
	P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
	P337+P317	If eye irritation persists: Get medical help.
	P304+P340	If inhaled: Remove person to fresh air and keep comfortable for breathing.
Disposal:	P342+P316	If experiencing respiratory symptoms: Get emergency medical help immediately.
	P391	Collect spillage.
	P501	Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards Not Otherwise Classified: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving therapy with β -lactams. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. When heated it may emit toxic fumes.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Weight %	CAS No.
Meropenem Trihydrate	~85%	119478-56-7
Sodium Carbonate	~15%	497-19-8

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.

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4 FIRST AID MEASURES

GENERAL:	Remove from exposure. Remove contaminated clothing. Persons 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.
INHALATION:	Move to fresh air and monitor breathing. Obtain medical attention for symptoms of difficulty in breathing and wheeziness, however minor.
EYES:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain medical attention.
SKIN:	Take off all contaminated clothing immediately. After contact with skin, wash immediately with mild soap and water. Obtain medical attention in case of irritation.
INGESTION:	Wash out mouth with water and give 200-300ml of water to drink. Do not attempt to give any solid or liquid by mouth If the exposed subject is unconscious or semi-unconscious. Do not induce vomiting as a First-Aid measure. Obtain medical attention.

Most important symptoms and effects; both acute and delayed

OVERVIEW:	Refer to Section 2 and Section 11.
Indication of any immediate medical attention and special treatment needed:	Symptomatic treatment and supportive therapy as indicated. For further details, consult the prescribing information.

5 FIRE FIGHTING MEASURES

Extinguishing Media:	Water spray, foam, dry powder or CO ₂ . Avoid high pressure media which could cause the formation of a potentially explosive dust-air mixture.
Special hazards arising from the substance or mixture:	If involved in a fire, it may burn and emit noxious and toxic fumes. Avoid breathing dust / fume / gas / mist / vapors / spray.
Advice for Fire-Fighters:	A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Ensure suitable personal protection during removal of spillages. See Section 8. Ensure adequate ventilation. In case of accident, avoid breathing dust from damaged or crushed container. Avoid contact with eyes and skin.
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Environmental precautions

Prevent entry into drains, sewers or watercourses. Collect spillage.

Methods and material for containment and cleaning up

Avoid dust generation. Transfer spilled vials to a suitable container for disposal. Wash the spillage area with water only after collection of material. Avoid use of oxidizing agents to wash the affected areas. Avoid release to the environment. See section 13.

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
Specific end use(s)**

Keep container tightly closed. Keep away from drains. Store below 25°C. Avoid exposure to heat sources. Avoid humidity. See prescribing information.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure
Limit:

<u>CAS No.</u>	<u>Ingredient</u>	<u>Value</u>	<u>Control Parameters</u>
119478-56-7	Meropenem Trihydrate	300µg /m ³	The exposure should be kept as low as possible below this level to protect against respiratory sensitization.

EXPOSURE CONTROLS
Respiratory:

Use a self-contained breathing apparatus if a risk assessment indicates this is necessary.

Eyes:

Use goggles to protect against direct contact with the substance products if a risk assessment indicates this is necessary

Skin:

Use impervious clothing to protect against direct contact with the product products if a risk assessment indicates this is necessary. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Engineering Controls:

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or water courses. See Section 6 for environmental precautions.

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Other Work Practices: The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration. Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Solid, crystalline powder	APPEARANCE:	White to light yellow powder
UPPER FLAMMABILITY LIMIT:	No data available	LOWER FLAMMABILITY LIMIT:	No data available
EXPLOSIVE LIMIT:	40 g/m ³	ODOR:	No data available
VAPOR PRESSURE:	No data available	ODOR THRESHOLD:	No data available
VAPOR DENSITY:	No data available	pH:	7.3-8.3 (5% solution)
RELATIVE DENSITY:	No data available	MELTING POINT:	No data available
FREEZING POINT:	No data available	SOLUBILITY:	No data available
INITIAL BOILING POINT:	627.4°C at 760 mmHg	BOILING RANGE:	No data available
FLASH POINT:	333.2°C	EVAPORATION RATE:	No data available
FLAMMABILITY:	No data available	PARTITION COEFFICIENT (N-OCTANOL / WATER)	-1.25
AUTO-IGNITION TEMPERATURE:	Layer (LIT): No ignition up to 400°C. Cloud (MIT): No ignition up to 480°C.	DECOMPOSITION TEMPERATURE:	No data available
VISCOSITY:	No data available		

10 STABILITY AND REACTIVITY

Reactivity: No data available.
Chemical Stability: Stable under normal circumstances.
Possibility of Hazardous reactions: No data available.

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Conditions to avoid:

Protect from moisture. Store in a dry place. Avoid accumulation of electrostatic charge. Connect to the circuit ground. Keep away from open flames, heat and direct lighting.

Incompatible Materials:

Avoid exposure to oxidizing agents.

Hazardous decomposition products:

See section 5, "Special hazards arising from the substance or mixture:".

11 TOXICOLOGICAL INFORMATION

ACUTE TOXICITY – CEFAZOLIN SODIUM

Measurement	Species	Dose	Route	Toxic Effects
LD50	No data available	No data available	Intraperitoneal	No data available
LD50	No data available	No data available	Intravenous	No data available
LD50	No data available	No data available	Oral	No data available
LD50	No data available	No data available	Subcutaneous	No data available
LD50	No data available	No data available	Inhalation	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.

Likely routes of exposure:	Inhalation, ingestion, eye contact, dermal contact.
Symptoms of exposure:	Eye, skin, and respiratory irritation may occur.
Delayed, immediate, chronic effects from short- and long-term exposure:	May cause sensitization by inhalation and dermal contact.
Carcinogen status:	No data available.

12 ECOLOGICAL INFORMATION

Toxicity

Product/Ingredient Name	Result	Species	Exposure
Meropenem Trihydrate	EC50 > 900 mg/L	Daphnia magna	48 hours
	EC50 > 100 mg/L	Algae – Pseudokirchneriella subcapitata	72 hours
	EC50 0.026 mg/L	Blue-green Algae – Microcystis aeruginosa	72 hours

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Persistence and degradability:

Not rapidly biodegradable.

Bioaccumulation potential:

The substance has low potential for bioaccumulation.

Soil mobility:

The substance has low mobility in soil (pH 7.7, Koc 220). The substance has moderate mobility in soil (pH 5.8, Koc 1121). The substance has high mobility in soil (pH 5.0, Koc 21724).

Other adverse events:

No data available.

13 DISPOSAL CONSIDERATIONS

Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. All waste should be characterized. Do not discharge into the sewer system or the environment. 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.

Contaminated packaging

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

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 Reportable Quantity – No
 SARA 302 Extremely Hazardous Substances Reportable Quantity – No
 SARA 313 – No
 OSHA Substance Specific – No
 EU EINECS / ELINCS List – 207-838-8
 Prop 65 – 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 1.0 – New Format
 Version 2.0 – Updated format and information in sections 1-13, 15-16

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