

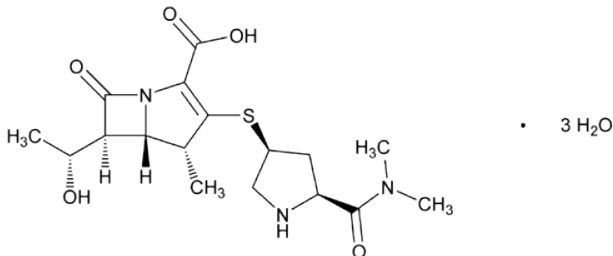
## 1 PRODUCT AND COMPANY INFORMATION

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

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

**Primary Component/ Active Ingredient:** Meropenem Trihydrate, USP

**Structure:**



**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, [4*R*-[3(3*S*\*,5*S*\*),4*a*,5*b*,6*b*(*R*\*)]]-; (2) (4*R*,5*S*,6*S*)-3-[[[(3*S*,5*S*)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1*R*)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid, trihydrate.

**Molecular Formula:** C<sub>17</sub>H<sub>25</sub>N<sub>3</sub>O<sub>5</sub>S·3H<sub>2</sub>O

**UNII Code:** UNII-FV9J3JU8B1

**CAS Number:** 119478-56-7

**Chemical Family:** Beta-lactam

**Product Use:** Antibacterial

**Product Type:** Pharmaceutical

**Container Information:** Vials

**Customer Service Phone Number:** +1-888-493-0861

**Emergency Phone Number:** +1-866-562-4708 (ProPharma)

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## 2 HAZARDS IDENTIFICATION

<b>Classification of Substance or Mixture:</b>	Eye Irritation, 2, H319:	Causes serious eye irritation:
	Skin Sensitization, 1B, H317	May cause allergic skin reaction
	Respiratory Sensitization, 1B, H34	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	Acute Aquatic Toxicity, 1, H400	Very toxic to aquatic life
	Chronic Aquatic Toxicity, 1, H410	Very Toxic to aquatic life with long lasting effects
<b>Label Elements:</b>	Signal Word: DANGER	



**[Prevention]:**

- P261: Avoid breathing dust / fume / gas / mist / vapors / spray.
- P273: Avoid release to the environment.
- P280: Wear protective gloves / eye protection / face protection.
- P285: In case of inadequate ventilation wear respiratory protection.
- P391: Collect spillage.
- P501: Dispose of contents/container to an approved incineration plant.

**[Response]:**

- P302+352: IF ON SKIN: Wash with plenty of soap and water.
- P304+341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P313: Get medical advice / attention.
- P321: Specific treatment (see information on this label).
- P333+313: If skin irritation or a rash occurs: Get medical advice / attention.
- P342+311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.
- P363: Wash contaminated clothing before reuse.

**[Storage]:**

No GHS storage statements

**[Disposal]:**

P501 Dispose of contents / container in accordance with local / national regulations.

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### 3 COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
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.

### 4 FIRST AID MEASURES

<b>GENERAL:</b>	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.
<b>INHALATION:</b>	Remove patient from exposure, keep warm and at rest. Obtain medical attention for symptoms of difficulty in breathing and wheeziness, however minor.
<b>EYES:</b>	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
<b>SKIN:</b>	Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of water. Obtain medical attention.
<b>INGESTION:</b>	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.

#### Most important symptoms and effects; both acute and delayed

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

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## 5 FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Water spray, foam, dry powder or CO <sub>2</sub> . Avoid high pressure media which could cause the formation of a potentially explosive dust-air mixture.
<b>Special hazards arising from the substance or mixture:</b>	If involved in a fire, it may burn and emit noxious and toxic fumes. Avoid breathing dust / fume / gas / mist / vapors / spray.
<b>Advice for Fire-Fighters:</b>	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 MEASURE

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Environmental precautions</b>	Prevent entry into drains, sewers or watercourses. Collect spillage.
<b>Methods and material for containment and cleaning up</b>	Avoid dust generation. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal. Avoid release to the environment. See section 13.

## 7 HANDLING AND STORAGE

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep container tightly closed. See product label for additional information.
<b>Specific end use(s)</b>	See prescribing information.

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## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### CONTROL PARAMETERS:

<u>CAS No.</u>	<u>Ingredient</u>	<u>Value</u>	<u>Control Parameters</u>
119478-56-7	Meropenem Trihydrate	0.1mg / m <sup>3</sup>	LTEL 8hr TWA This value is not a health based OEL. The exposure should be kept as low as possible below this level to protect against respiratory sensitization

### Carcinogen Data

<u>CAS No.</u>	<u>Ingredient</u>	<u>Source</u>	<u>Control Parameters</u>
119478-56-7	Meropenem Trihydrate	N/A	No information available

### EXPOSURE CONTROLS

<b>Respiratory:</b>	Use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection
<b>Eyes:</b>	Use goggles to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.
<b>Skin:</b>	Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. 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.
<b>Engineering Controls:</b>	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.
<b>Other Work Practices:</b>	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.

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## 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE:</b>	Solid (Crystalline Powder)	<b>SPECIFIC GRAVITY:</b>	Not Available
<b>APPEARANCE:</b>	White to off-white powder.	<b>EVAPORATION RATE:</b>	Not Measured
<b>BOILING POINT:</b>	Not Measured	<b>MELTING POINT:</b>	Not Measured
<b>VAPOR PRESSURE:</b>	Not Measured	<b>SOLUBILITY IN WATER:</b>	Sparingly Soluble
<b>VAPOR DENSITY:</b>	Not Measured	<b>pH:</b>	Not Measured

## 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>	No data available.
<b>Conditions to avoid:</b>	No conditions producing hazardous situations known.
<b>Incompatible Materials:</b>	No data available.
<b>Hazardous decomposition products:</b>	No hazardous decomposition products are known.

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## 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
Meropenem Trihydrate	No Data Available	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.

<u>Classification</u>	<u>Category</u>	<u>Hazard Description</u>
Acute toxicity (Injection)	---	May produce headache, diarrhoea, drowsiness, skin rashes or cough.
Acute toxicity (skin)	---	Unlikely to cause skin irritation.
Acute toxicity (inhalation)	---	May cause effects as described under repeated exposure (STOT).
Skin corrosion/irritation	---	Unlikely to cause skin irritation.
Serious eye damage/irritation	---	Causes serious eye irritation.
Respiratory sensitization	1	May cause effects as described under repeated exposure (STOT).
Skin sensitization	1	May cause sensitisation by inhalation and skin contact. Symptoms may include wheeziness and difficulty in breathing.
Germ cell mutagenicity	---	Not considered to be a genotoxic.
Carcinogenicity	---	No information available.
Reproductive toxicity	---	There is no evidence of a teratogenic potential or any other adverse effects on reproductive function. The substance may be excreted in breast milk at low concentrations.
STOT-single exposure	---	May cause effects as described under repeated exposure.(STOT).
STOT-repeated exposure	---	Repeated exposure by inhalation may produce hypersensitivity reactions as described above.
Aspiration hazard	---	No information available.

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## 12 ECOLOGICAL INFORMATION

### Toxicity

#### Aquatic Toxicity

Very Toxic to aquatic life with long lasting effects. No information on this formulation. The following information refers to active ingredient

INGREDIENT	48 hr EC50 Daphnia Magna, mg/L	72 hr EC50 Blue-Green Algae, mg/L	ErC50 Algae, mg/L
Meropenem Trihydrate	>900	0.026	Not available
Effect on Effluent Treatment	There is no evidence of inhibition to the aerobic treatment process at a concentration of > 100 mg/l.		

**Persistence and degradability:** Not rapidly degradable

**Bioaccumulative potential:** The substance has low potential for bioaccumulation

**Mobility in soil:** 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).

**Results of PBT and vPvB assessment:** This product contains no PBT/vPvB chemicals.

**Other adverse effects:** No data available.

## 13 DISPOSAL CONSIDERATIONS

**Waste treatment methods** Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Dispose of contents/ container to an approved incineration plant.

## 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  
EU EINECS / ELINCS List – 207-838-8  
Proposition 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 PUROPOSE). 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.

The full text of the phrases appearing in Section 3 is:

H317 May cause an allergic skin reaction.  
H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.  
H319 Causes serious eye irritation.  
H319 Causes serious eye irritation.  
H400 Very toxic to aquatic life  
H410 Very toxic to aquatic life with long lasting effects  
H319 Causes serious eye irritation.

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