Yangzhou Sunchem Co.,Ltd.

Material Safety Data Sheet

Meropenem

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And

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Product Name Meropenem for Injection, USP

Synonyms (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.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Meropenem

Chemical Formula $C_{17}H_{25}N_3O_5S \cdot 3H_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Meropenem Trihydrate	85	119478-56-7	CL5446507
Sodium Carbonate	15	497-19-8	VZ4050000

3. HAZARD INFORMATION

Emergency Overview Meropenem for Injection, USP is a powder that contains meropenem, a carbapenem beta-lactam antibacterial with actions and uses similar to those of imipenem. Clinically, it is used to treat infections caused by susceptible Gram-positive and Gram-negative bacteria. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract, and a potential sensitizer which may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

Occupational Exposure

Potential

Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms None known from occupational exposure. In clinical use, the most common adverse effects of meropenem include headache, nausea, diarrhea, vomiting, rash, fever, hypotension, seizures, dizziness, pruritus, urticaria, somnolence, elevated liver enzymes, and elevated BUN and

creatinine levels. Some patients with a history of penicillin hypersensitivity have experienced severe hypersensitivity reactions when treated with another beta-lactam antibiotic.

Medical Conditions

Aggravated by Exposure

Pre-existing hypersensitivity to meropenem; penicillins, cephalosporins or other lactamlike antibiotics; pre-existing gastrointestinal, skin, hematopoietic, or liver ailments.

Carcinogen Lists: **IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

4. FIRST AID MEASURES

Eye Contact 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 Contact 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.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability Non-flammable powder. However, powder may be ignitable under high temperature.

Fire & Explosion

Hazard

None anticipated. As with all powders, minimize the creation of dusty environments.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting

Procedures

No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and

Disposal

For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions are required for hazard controls. Employees with known allergies to penicillin and cephalosporin antibiotics should consult a health and/or safety professional prior to working with open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**	**Other Limits**
Meropenem Trihydrate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	Not Established
Sodium Carbonate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit

ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

EEL: Employee Exposure Limit.

TWA: 8 hour Time Weighted Average; STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State Meropenem is a white to pale yellow crystalline powder; solutions

vary
from colorless to yellow depending on the concentration.
Odor NA
Odor Threshold: NA
pH: The pH of freshly constituted aqueous solutions is between 7.3 and 8.3.
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive
Limits:NA
Vapor Pressure NA
Vapor Density (Air =1) NA
Evaporation Rate NA
Specific Gravity NA
Solubility Soluble in water
Log Partition coefficient: n-octanol/water: NA
Auto-ignition temperature NA
Decomposition temperature NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.
Chemical Stability Stable under standard use and storage conditions.
Hazardous Reactions Not determined
Conditions to avoid Strong oxidizers and strong bases
Incompatibilities Not determined
Hazardous Decomposition
Products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), or sulfur oxides (SOx).
Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingredient(s)	**Percent**	**Test Type**	**Route of Administration**	**Value**		
Meropenem Trihydrate	**100**	LD50	Oral	NA	NA	NA
Meropenem	**100**	LD50	Oral	>5000	mg/kg	Rat, Mouse
Meropenem	**100**	LD50	Intravenous	2850 2650	mg/kg mg/kg	Rat, Mouse
Sodium	**100**	LD50	Oral	4090	mg/kg	Rat, Mouse

Carbonate				6600	mg/kg	

LD50: Dosage that produces 50% mortality.

Aspiration Hazard None anticipated from normal handling of the intact product.

Dermal

Irritation/Corrosion

None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to mucous membranes and the respiratory system.

Ocular

Irritation/Corrosion

None anticipated from normal handling of the intact product. However, inadvertent contact of this product formulation with eyes may produce irritation with redness and discomfort.

Dermal or

Respiratory

Sensitization

None anticipated from normal handling of the intact product. The active ingredient in this product is a potential sensitizer and may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. If known to be allergic to penicillins or cephalosporins, consult a health or safety professional prior to handling open containers of this product.

Reproductive Effects Reproductive studies conducted with meropenem in rats at dosages up to 1000 mg/kg/day, and cynomolgus monkeys at dosages of up to 360 mg/kg/day. These studies revealed no evidence of impaired fertility or harm to the fetus due to meropenem, although there were slight changes in fetal body weight at dosages of 250 mg/kg/day.

Mutagenicity Genetic toxicity studies were performed with meropenem using the bacterial reverse mutation test, the Chinese hamster ovary HGPRT assay, cultured human lymphocytes cytogenic assay, and the mouse micronucleus test. There was no evidence of mutagenic potential found in any of these tests.

Carcinogenicity Long term studies to evaluate carcinogenic potential of meropenem have not been conducted.

Target Organ Effects Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity Not determined for product. Information for ingredients is as follows:

LC50 = 320 mg/L; 96 Hr.; static Conditions, for Bluegill/Sunfish for sodium carbonate

Persistence/Biodegradability Not determined for product.

Bioaccumulation Not determined for product.

Mobility in Soil Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Disposal should be performed in accordance with federal, state or local regulatory requirements.

Container Handling and

Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS: Not Regulated
Proper shipping name: NA
Hazard class: NA
UN number: NA
Packing group: NA
Reportable quantity: NA
ICAO/IATA STATUS Not regulated
Proper shipping name: NA
Hazard class: NA
UN number: NA
Packing group: NA
Reportable quantity: NA
IMDG STATUS Not regulated
Proper shipping name: NA
Hazard class: NA
UN number: NA
Packing group: NA
Reportable quantity: NA

15. REGULATORY INFORMATION

U.S. TSCA Status This product is exempt. However, sodium carbonate is listed on the U.S. TSCA inventory.
U.S CERCLA Status Not listed
U.S. SARA 302 Status
U.S. SARA 313 Status
Not listed
Not listed
U.S. RCRA Status Not listed
U.S. PROP 65 (Calif.) Not listed

Notes:

TSCA, Toxic Substance Control Act;

CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act;

SARA, Superfund Amendments and Reauthorization Act;

RCRA, US EPA, Resource Conservation and Recovery Act;

Prop 65, California Proposition 65

U.S. OSHA Classification Possible Irritant
Possible Sensitizer
Target Organ Toxin

GHS Classification* *Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

Prevention: Avoid breathing dust/vapors/spray.

In case of inadequate ventilation wear respiratory protection as specified by the manufacturer/ supplier or the competent authority.

Wear protective gloves as specified by the manufacturer/supplier or the competent authority.

Contaminated work clothing should not be allowed out of the workplace.

Response: IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical advice/attention. Wash contaminated clothing before reuse.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

If skin irritation occurs, get medical advice/attention.

Get medical attention if you feel unwell.

EU Risk Phrases: R36/37/38 - Irritating to eyes, respiratory system and skin

R42/43 - May cause sensitization by inhalation and skin contact

EU Safety Phrases: S22: Do not breathe dust

S23: Do not breathe vapor or spray

S25: Avoid contact with eyes

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value

CAS Chemical Abstracts Service Number

CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act

DOT US Department of Transportation Regulations

EEL Employee Exposure Limit

IATA International Air Transport Association

LD_{50} Dosage producing 50% mortality

NA Not applicable/Not available

NE Not established

NIOSH National Institute for Occupational Safety and Health

OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit

Prop 65 California Proposition 65

RCRA US EPA, Resource Conservation and Recovery Act

RTECS Registry of Toxic Effects of Chemical Substances

SARA Superfund Amendments and Reauthorization Act

STEL 15-minute Short Term Exposure Limit

TSCA Toxic Substance Control Act

TWA 8-hour Time Weighted Average

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use.