



MATERIAL SAFETY DATA SHEET

Product Name: Meropenem for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887
Hospira, Inc., Non-Emergency 224-212-2055

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 lactam-like 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	<p>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.</p> <p>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.</p>
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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

Component	Exposure limits			
	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	Units	Species
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 Carbonate	100	LD50	Oral	4090 6600	mg/kg mg/kg	Rat Mouse

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

Notes: DOT - US Department of Transportation Regulations

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 Not listed

U.S. SARA 313 Status 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:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Respiratory and Skin Sensitization	Target Organ Toxicity
Hazard Category	Unclassified	2B	1	2
Hazard Symbol	NA	NA		
Signal Word	NA	Warning	Danger	Warning
Hazard Statement	NA	Causes eye irritation	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	May cause damage to the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver through prolonged or repeated exposure.

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.

15. REGULATORY INFORMATION: continued

EU Classifications*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substances meropenem.

Classification(s):	Irritant	Skin Sensitizer	Respiratory Sensitizer
Symbol			
Indication of Danger	Xi	Xi	Xn
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

MSDS Coordinator: Hospira GEHS

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