

SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Brooks Srteriscience Ltd. Village-Manglej, Nareshwar Road, Off NH-8, Taluka-Karjan, Vadodara 391210, Gujarat, India. Tel.: 91- 2666 - 235500
Product Name	<u>Meropenem for Injection</u>
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. HAZARD(S) IDENTIFICATION

Emergency Overview	Meropenem for Injection is a powder containing 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, nervous system, skin, hematopoietic system, and liver.
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U.S. OSHA GHS Classification

Physical Hazards	Hazard Class Not Classified	Hazard Category Not Classified
Health Hazards	Hazard Class Eye Damage / Irritation Sensitization – Skin Sensitization - Respiratory STOT - RE	Hazard Category 2A 1 1

Label Element(s)

Pictogram



Signal Word

Danger

Hazard Statement(s)

Causes serious eye irritation
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause damage to organ through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Do not breathe dust, vapor or spray
In case of inadequate ventilation, wear respiratory protection
Wear eye protection/face protection
Wear protective gloves
Wash hands thoroughly after handling

Response

Contaminated work clothing must not be allowed out of the workplace.
Get medical attention if you feel unwell

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor

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 ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Meropenem	Sodium Carbonate
Chemical Formula	C ₁₇ H ₂₅ N ₃ O ₅ S•3H ₂ O	CO ₃ Na ₂

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Meropenem Trihydrate	91	119478-56-7	CL5446507
Sodium Carbonate	8	497-19-8	VZ4050000

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

None anticipated for this product. However, many organic powders will combust at elevated temperatures.

Fire & Explosion Hazard

None anticipated for this product. Avoid the creation of dusty environments.

Extinguishing Media

As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures

No special provisions required beyond normal firefighting 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 control 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 handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits		
	OSHA-PEL	ACGIH-TLV	AIHA WEEL
Meropenem Trihydrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Sodium Carbonate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 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.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.TWA:
8-hour Time Weighted Average.

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
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Soluble in water
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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 (CO _x), nitrogen oxides (NO _x), sulfur oxides (SO _x), and oxides of sodium (Na _x O _x).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the ingredients is as follows:

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.

11. TOXICOLOGICAL INFORMATION: continued

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 anticipated from normal handling of this product. In clinical use, the most common adverse effects of meropenem include headache, nausea, diarrhea, vomiting, rash, seizures, pruritus, urticaria, thrombocytosis, abdominal pain, and elevated liver enzymes. Some patients with a history of penicillin hypersensitivity have experienced severe hypersensitivity reactions when treated with another beta-lactam antibiotic.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this 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 this 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 this 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	None anticipated from normal handling of this product. Reproductive studies conducted with meropenem in rats at dosages up to 750 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. There was increased evidence of abortions at 500 mg/kg in a preliminary study in monkeys.
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	The carcinogenic potential of meropenem has not been evaluated.
Carcinogen Lists	IARC: Not listed NTP: Not listed OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the gastrointestinal system, 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. Further, disposal should be performed in accordance with the 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

ADR/ADG/ 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

US TSCA Status	Exempt. However, sodium carbonate is listed on the U.S. TSCA inventory.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US 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

15. REGULATORY INFORMATION: continued

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe dust, vapor or spray
 In case of inadequate ventilation, wear respiratory protection
 Wear eye protection/face protection
 Wear protective gloves
 Wash hands thoroughly after handling
 Contaminated work clothing must not be allowed out of the workplace

Response

Get medical attention if you feel unwell

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor

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 ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

EU Classification*

Classification(s)
Symbol
Indication of Danger
Risk Phrases
Safety Phrases

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

NA
 NA
 NA

R42/43: May cause sensitization by inhalation and skin contact
 S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes
 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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average