

Meropenem for Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Meropenem for Injection
Other means of identification : NDC CODE: 55150-207-20, 55150-208-30 (for 500 mg, 1g)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Eye Irrit. 2A H319
Resp. Sens. 1 H334
Skin Sens. 1 H317
STOT RE 2 H373

Full text of classification categories and H statements : see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US) : Danger

Hazard statements (GHS-US) : H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (GHS-US) : P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash thoroughly after handling
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P284 - [In case of inadequate ventilation] wear respiratory protection
P302+P352 - If on skin: Wash with plenty of water
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P314 - Get medical advice/attention if you feel unwell
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P342+P311 - If experiencing respiratory symptoms: Call a poison center/doctor
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

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SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Meropenem trihydrate	(CAS No) 119478-56-7	> 70	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Disodium carbonate	(CAS No) 497-19-8	< 30	Not classified

Full text of classification categories and H statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- First-aid measures after 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.
- First-aid measures after 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.
- First-aid measures after ingestion : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Symptoms/injuries after skin contact : May cause an allergic skin reaction.
- Symptoms/injuries after eye contact : Causes serious eye irritation.
- Symptoms/injuries after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.

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Methods for cleaning up : 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.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : No special handling required under conditions of normal product use.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : No special storage required for hazard control.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Meropenem trihydrate (119478-56-7)

Not applicable

Disodium carbonate (497-19-8)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use latex or nitrile gloves.
Eye protection : In case of dust production: protective goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Powder.
Color : White to pale yellow
Odor : None
Odor threshold : No data available
pH : 7.3 - 8.3 (Aqueous solution)
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability (solid, gas) : No data available
Vapor pressure : No data available
Relative vapor density at 20 °C : No data available
Relative density : No data available
Solubility : Soluble in water
Log Pow : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available

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Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None

10.5. Incompatible materials

Strong oxidizers and strong bases

10.6. Hazardous decomposition products

During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), sulfur oxides (SOx), and oxides of sodium (Na_xOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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LD50 oral rat	> 5314 mg/kg

Disodium carbonate (497-19-8)	
LD50 oral rat	4090 mg/kg
LC50 inhalation rat (mg/l)	2300 mg/m ³ (Exposure time: 2 h)
ATE US (oral)	4090.000 mg/kg

Skin corrosion/irritation	: Not classified pH: 7.3 - 8.3 (Aqueous solution)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 7.3 - 8.3 (Aqueous solution)
Respiratory or skin sensitization	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. 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.
Germ cell mutagenicity	: Not classified. 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	: Not classified
Reproductive toxicity	: Not classified. 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.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified

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SECTION 12: Ecological information

12.1. Toxicity

Disodium carbonate (497-19-8)	
LC50 fish 1	300 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	265 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	310 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Disodium carbonate (497-19-8)	
BCF fish 1	(no bioaccumulation)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Disodium carbonate (497-19-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State regulations

No additional information available

SECTION 16: Other information

Full text of H-phrases:

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H373	May cause damage to organs through prolonged or repeated exposure

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product