

Ertapenem for Injection, USP

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Ertapenem for Injection, USP NDC 55150-282-20 (carton of 10)

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
279 Princeton-Hightstown Rd.
E. Windsor, NJ 08520
T 888-238-7880

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

Resp. Sens. 1 H334
Comb. Dust

Full text of hazard classes 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) : May form combustible dust concentrations in air
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (GHS-US) : P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P284 - [In case of inadequate ventilation] wear respiratory protection
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing
P342+P311 - If experiencing respiratory symptoms: Call a poison center/doctor/...
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

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Ertapenem sodium	(CAS No) 153773-82-1	70 - 90	Not classified

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Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If not breathing, give artificial respiration.
- First-aid measures after skin contact : Wash with water and soap. Get medical attention if symptoms occur.
- First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water. Get medical attention if irritation develops and persists.
- First-aid measures after ingestion : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

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 skin irritation.
- Symptoms/injuries after eye contact : May cause 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 water spray, alcohol resistant foam, carbon dioxide, or dry chemical.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

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.
- Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

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 : Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep container tightly closed. Do not store lyophilized powder above 25°C (77°F).

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ertapenem sodium (153773-82-1)

Not applicable

8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use chemical resistant gloves to minimize skin contact.
Eye protection	: In case of dust production: protective goggles.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Lyophilized powder
Color	: Off-white to white
Odor	: Odorless.
Odor threshold	: No data available
pH	: No data available
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	: No data available
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
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.

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10.5. Incompatible materials

Oxidizing agents.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity – single exposure	: Not classified
Specific target organ toxicity – repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging 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

No additional information available

15.2. US State regulations

No additional information available

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SECTION 16: Other information

Full text of H-phrases:

Comb. Dust	Combustible Dust
Resp. Sens. 1	Respiratory sensitisation Category 1
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

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