

Rocuronium Bromide Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Rocuronium Bromide Injection
Other means of identification : 50 mg/5 mL vials NDC 55150-225-05
100 mg/10 mL vials NDC 55150-226-10

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
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

Not classified

2.2. Label elements

GHS-US labeling

No labeling applicable

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
Rocuronium bromide	(CAS No) 119302-91-9	1	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. The primary treatment is maintenance of a patent airway and controlled ventilation until recovery of normal neuromuscular function is assured. Once evidence of recovery from neuromuscular block is observed, further recovery may be facilitated by administration of an anti-cholinesterase agent (e.g., neostigmine, edrophonium) in conjunction with an appropriate anti-cholinergic agent (see package insert).

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

Symptoms/injuries after inhalation	: None anticipated from normal handling of this product.
Symptoms/injuries after skin contact	: None anticipated from normal handling of this product.
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 extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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5.3. Advice for firefighters

Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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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	: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill 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.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: No special storage required for hazard control.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Rocuronium bromide (119302-91-9)

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	: 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.
Skin and body protection	: Wear suitable working clothes.

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Respiratory protection : No protection is ordinarily required under normal conditions of use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : Colorless to yellow/orange
Odor : odorless
Odor threshold : No data available
pH : 3.8 - 4.2
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

Not determined.

10.5. Incompatible materials

Not determined.

10.6. 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), and hydrogen bromide (HBr).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified
Skin corrosion/irritation : Not classified
pH: 3.8 - 4.2

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Serious eye damage/irritation	: Not classified pH: 3.8 - 4.2
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-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

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

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

SECTION 16: Other information

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