SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Tenth Revised Edition UNITED NATIONS New York and Geneva, 2023

Rocuronium Bromide Injection 10mg/mL

1. IDENTIFICATION

GHS Product identifier: Rocuronium Bromide Injection

Product code: #

Chemical Description:

[(2*S*,3*S*,5*S*,8*R*,9*S*,10*S*,13*S*,14*S*,16*S*,17*R*)-3-hydroxy-10,13-dimethyl-2-morpholin-4-yl-16-(1-prop-2-enylpyrrolidin-1-ium-1-yl)-2,3,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydro-1*H*-cyclopenta[a]phenanthren-17-yl] acetate;bromide

Other means of identification: -

Recommended use of the injection:

Rocuronium injection is used with general anesthesia medicines for rapid sequence intubation and routine tracheal intubation.

Restrictions on use: The product should be used only for the above-mentioned use and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: L74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Not classified as hazardous

Labelling - None

Classification	
Signal Word	**Not classified**
Hazard Statements:	No known significant effects or critical hazards
Precautionary Statements:	P273: Avoid release to the environment. P264: Wash hands and face thoroughly after handling. P280-Wear protective gloves, face protection. P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes. P391:Collect spillage.
Other hazards	None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Rocuronium bromide

Hazardous ingredients	CAS	Content (mg/ml)
Rocuronium bromide	119302-91-9	10.000 (1%)
Sodium Acetate Trihydrate	6131-90-4	2.000 (0.2%)
Sodium Chloride	7647-14-5	3.300 (0.3%)
Glacial Acetic Acid	64-19-7	q.s. to pH
Sodium hydroxide	1310-73-2	q.s. to pH
Water for Injection	7732-18-5	q.s. to 1 ml

4. FIRST-AID MEASURES

Inhalation

Move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water.

Eye contact

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention

Ingestion

If this product is swallowed, call physician or Poison Control Centre. Rinse mouth with water. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, dry chemical or carbon dioxide.

Fire/explosion hazard

Product is not explosive.

Specific hazards arising from the chemical

None anticipated for the mixture.

Hazardous thermal decomposition products

None.

Personal protection

Appropriate protective clothing. Fire-fighters must wear self-contained breathing apparatus for fire-fighting if necessary.

Special exposure hazards

Do not release chemically contaminated water into drains, soil, or surface water. Dispose contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Wear respiratory protection.

Environmental precautions

Prevent products from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed).

Conditions for safe storage
Keep away from heat/sparks/open flames/hot surfaces – No smoking.
Storage facilities
Store away from light, in a cool, dry area. Keep tightly closed.
Segregation
Store locked up.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values
Components with occupational exposure limits

CAS No	Name	Limits
119302-91-9	Rocuronium Bromide	TLV-C (MSD internal) - 4 µg/m³ (OEB 4) Pfizer OEL TWA-8 Hr: 20 µg/m³
1310-73-2	Sodium hydroxide	ACGIH Ceiling - 2 mg/m³
64-19-7	Acetic acid	STEL 15 ppm
7647-01-0	Hydrochloric acid	ACGIH Ceiling - 2 ppm

Occupational exposure controls

Appropriate engineering controls
Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
General Personal Protection
Goggles, gloves, protective clothing.
Respiratory protection
Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
Hand protection
Protective gloves.
Eye protection
Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts.
Skin and body protection
Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose off
contaminated gloves after use in accordance with applicable laws and good laboratory practices.
Wash and dry hands.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear liquid
Form: Injection
Colour: Clear
Odour: Odourless
pH: 4.0 (3.8 - 4.2)
Melting point: Not applicable
Boiling point: 100 °C
Flash point: Not applicable
Flammability (solid): Not available
Vapour pressure: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Density: Around 1
Solubility in water: Soluble.
Solubility in solvents: Soluble in dehydrated alcohol
n-Octanol/Water Partition Coefficient: 0.5 at 20°C
Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Chemical stability
Stable under recommended storage conditions.

Conditions to avoid
None known.

Materials to avoid
Under normal conditions of storage and use, hazardous reactions will not occur. Can react with strong oxidising agents.

Hazardous decomposition products
Under normal conditions of storage and use, hazardous decomposition products should not be produced. Formation of toxic gases is possible during heating or fire which can inclue oxides of carbon, nitrogen and Hydrogen Bromide.

11. TOXICOLOGICAL INFORMATION

Acute toxicity - Rocuronium bromide

Acute toxicity (other routes of administration)
LD_{50} (Rat): > 2.000 mg/kg

Application Route: Oral
LD_{50} (Rat): 0.3 mg/kg
Application Route: Intravenous
The active ingredient is classified as category 4 for acute toxicity.

Acetic acid = 3310 mg/kg (rat)
Sodium hydroxide = 325 mg/kg
Sodium acetate = 325 mg/kg

Based on the percentage of ingredients in the mixture, it is not classified for acute toxicity.

Primary Irritation:
Skin/eye
Sodium hydroxide - skin Corr. 1A
Acetic acid - skin corr. 1A

Mixture is not classifiable for skin/eye irritation.

Respiratory or Skin sensitization
Mixture is not classifiable for respiratory or skin sensitization

CMR consideration:
Germ cell mutagenicity:
Not mutagenic. Mixture not classifiable. Weight of evidence does not support classification as a germ cell mutagen.

Genotoxicity:
Rocuronium Bromide
Bacterial Mutagenicity (Ames) Negative
Chromosome Aberration Human Lymphocytes Negative
Micronucleus Rat Bone marrow

Carcinogenicity
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. Not classifiable as human carcinogen.

Reproductive toxicity: Not classified based on available information

Rocuronium Bromide
Embryo / Fetal Development Rat Intravenous 0.3 mg/kg NOAEL Not teratogenic
Embryo / Fetal Development Rabbit Intravenous 0.02 mg/kg NOAEL Not teratogenic

Specific target organ toxicity single exposure: Mixture is not classifiable for STOT-SE

Specific target organ toxicity repeated exposure: Mixture is not classifiable for STOT-RE

Aspiration hazard:
GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Environmental properties for Rocuronium Bromide have not been thoroughly investigated.
Releases to the environment should be avoided.

Ecotoxicity
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Acetic acid
Fathead Minnow NPDES LC-50 96 hours 88 mg/L
Bluegill Sunfish NPDES LC-50 96 hours 75 mg/L
Goldfish NPDES LC-50 24 hours

Based on the information available, mixture is not classified for aquatic toxicity.

Persistence and degradability
No information available.

Bioaccumulative Potential
Not expected to bioaccumulate.

Other adverse effects
No data available
Additional information
Do not discharge products, uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal
All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or onsite wastewater treatment facility.

Contaminated packaging
Contaminated, empty containers must be disposed off as chemical waste.

14. TRANSPORT INFORMATION

DOT
Not regulated as dangerous goods.
IATA
Not regulated as dangerous goods.
IMDG
Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with the following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2023 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes – First edition

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