

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Rocuronium Bromide Injection
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: January 15, 2011
SDS Revision Date: June 08, 2023

SECTION 2 : HAZARD(S) IDENTIFICATION

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.

Potential Health Effects:

- Eye:** Contact with eyes may cause irritation.
- Skin:** May cause skin irritation.
- Inhalation:** May cause irritation of respiratory tract.
- Ingestion:** May cause irritation.

Signs/Symptoms: Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses may include: Possible adverse reactions include: Arrhythmia, tachycardia, nausea, vomiting, bronchospasm, wheezing, rash, pruritus. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a hypersensitivity to rocuronium bromide.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Rocuronium Bromide	119302-91-9	10 mg/ml	
Sodium Acetate Trihydrate	6131-90-4	2 mg/ml	
Sodium Chloride	7647-14-5	- for isotonicity. -	
Water for Injection	7732-18-5	- Quantity Sufficient. -	

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Note to Physicians: An antagonist (such as neostigmine, edrophonium) in conjunction with an appropriate anticholinergic agent can be given once evidence of recovery from the neuromuscular block is observed.

Other First Aid: For Adverse Event Information, please call Vigilance: (905) 770-3711.

SECTION 5 : FIRE FIGHTING MEASURES

Flammable Properties:	Combustible.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at refrigerated temperatures 2 to 8°C (36 to 46°F). Protect from freezing.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Ingredient	Guideline OSHA	Guideline ACGIH	Quebec Canada	Ontario Canada	Alberta Canada
Rocuronium Bromide	Not established.	Not established.	Not established.	Not established.	Not established.
Sodium Acetate Trihydrate	Not established.	Not established.	Not established.	Not established.	Not established.
Sodium Chloride	Not established.	Not established.	Not established.	Not established.	Not established.
Water for Injection	Not established.	Not established.	Not established.	Not established.	Not established.

Ingredient	British Columbia Canada				
Rocuronium Bromide	Not established.				
Sodium Acetate Trihydrate	Not established.				
Sodium Chloride	Not established.				
Water for Injection	Not established.				

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Clear to yellow.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	No Data
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.0
Molecular Formula:	Mixture
Molecular Weight:	609.70
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Reproductive Toxicity: Pregnancy Category C: Rocuronium caused acute symptoms of respiratory dysfunction in rabbits and rats. Teratogenicity was not observed in these animal species. There are no adequate and well-controlled studies in pregnant women. Rocuronium Bromide Injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Rocuronium Bromide :

Ingestion: Oral - Mouse LD50: 20 gm/kg
Oral - Rat LD50: 200 mg/kg

Other Toxicological Information: LD50 IV Rat: > 150 mcg/kg
LD50 IV Mouse: 50 mcg/kg
LD50 SC Rat: 400 mcg/kg
LD50 SC Mouse: 150 mcg/kg

Sodium Chloride :

RTECS Number: VZ4725000

Eye: Eye - Rabbit Standard Draize test.: 100 mg/24H
Eye - Rabbit Standard Draize test.: 10 mg (RTECS)

Skin: Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild]
Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]

Ingestion: Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Other Toxicological Information: Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability:

No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:

Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

IATA Shipping Name: Not Regulated.

IATA UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Canada WHMIS:

Controlled - Class: D2B Toxic

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: X

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SDS Revision Notes:

Added language in Section 14 - Transport Information to specify that this finished product is not regulated as a 'Dangerous Good' for transportation under ICAO/IATA - Dangerous Goods Regulations (as it is not regulated as a 'Hazardous Material' for transportation under U.S. DOT - Hazardous Materials Regulations either).

Disclaimer:

The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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