

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Rocuronium Bromide Injection

1.2 Recommended Use and Restrictions on Use

Use Of The Substance/Mixture : For professional use only

Restrictions On Use : No additional information available

1.3. Name, Address, and Telephone of the Responsible Party

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Reproductive toxicity, Category 2

H361

Specific target organ toxicity, Single exposure, Category 1

H370

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H361 - Suspected of damaging fertility or the unborn child.

H370 - Causes damage to organs (Neuromuscular system).

Precautionary Statements (GHS-US/CA)

: P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe mist, spray, or vapors.

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P280 - Wear eye protection, protective gloves, and protective clothing.

P308+P311 - IF exposed or concerned: Call a POISON CENTER or a doctor.

P308+P313 - IF exposed or concerned: Get medical advice or attention.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P405 - Store locked up.

P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

2.3 Hazards associated with known or reasonably anticipated uses

If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses

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should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.5 Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Rocuronium bromide	Pyrrolidinium, 1- [[2.beta.,3.alpha.,5.alpha.,16.beta.,17.beta.]-17-(acetyloxy)-3-hydroxy-2-(4-morpholinyl)androstan-16-yl]-1-(2-propenyl)-, bromide	(CAS-No.) 119302-91-9	0.1 - 1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 3 (Inhalation), H331 Repr. 2, H361 STOT SE 1, H370
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 2, H401
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE / Lye solution	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Corr. 1, H314 Eye Dam. 1, H318 STOT SE 1, H370 Aquatic Acute 3, H402

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the Hazardous Products Regulations (HPR) SOR/2022-272 and 29 CFR 1910.1200.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child. Causes damage to organs (Neuromuscular system).

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen bromide. Chlorides. Sodium oxides.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin and clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Oxidizing agent.

Storage Temperature: 20 – 25 °C (68 – 77 °F) Excursion permitted between 15 - 30 °C (59 - 86 °F) DO NOT FREEZE

7.3. Specific End Use(s)

For professional use only

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

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For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH® TLV® C	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA OSHA	OSHA PEL C	7 mg/m ³
USA OSHA	OSHA PEL C	5 ppm
USA NIOSH	NIOSH REL C	7 mg/m ³
USA NIOSH	NIOSH REL C	5 ppm
USA IDLH	IDLH	50 ppm
Alberta	OEL C	3 mg/m ³
Alberta	OEL C	2 ppm
British Columbia	OEL C	2 ppm
Manitoba	OEL C	2 ppm
New Brunswick	OEL C	2 ppm
Newfoundland & Labrador	OEL C	2 ppm
Nova Scotia	OEL C	2 ppm
Nunavut	OEL C	2 ppm
Northwest Territories	OEL C	2 ppm
Ontario	OEL C	2 ppm
Prince Edward Island	OEL C	2 ppm
Québec	Plafond (OEL C)	2 ppm
Saskatchewan	OEL C	2 ppm
Yukon	OEL C	7 mg/m ³
Yukon	OEL C	5 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH® TLV® C	2 mg/m ³
USA OSHA	OSHA PEL TWA	2 mg/m ³
USA NIOSH	NIOSH REL C	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³
British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³
Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond (OEL C)	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



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Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Color	: Colorless to yellow/orange
Odor	: No data available
Odor Threshold	: No data available
pH	: 2.8 – 3.2
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity, Kinematic	: No data available
Particle characteristics	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Oxidizing agent.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen bromide. Chlorides. Sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Eye Contact, Inhalation, Oral.

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

LD50 and LC50 Data:

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No additional information available

Skin Corrosion/Irritation: Not classified.

pH: 2.8 – 3.2

Eye Damage/Irritation: Not classified.

pH: 2.8 – 3.2

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Causes damage to organs (Neuromuscular system).

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Rocuronium bromide (119302-91-9)	
ATE US/CA (oral)	500.00 mg/kg body weight
ATE US/CA (dermal)	1,100.00 mg/kg body weight
ATE US/CA (gas)	700.00 ppmV/4h
ATE US/CA (vapors)	3.00 mg/l/4h
ATE US/CA (dust, mist)	0.50 mg/l/4h
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 – 277 mg/kg (Source: JAPAN_GHS)
LD50 Dermal Rabbit	> 5010 mg/kg (Source: JAPAN_GHS)
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h Source: JAPAN_GHS)
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
LD50 Dermal Rabbit	1350 mg/kg (Source: NLM_HSDB)
Hydrochloric acid (7647-01-0)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

12.2. Persistence and Degradability

Rocuronium Bromide Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Rocuronium Bromide Injection	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil

No additional information available

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12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Rocuronium Bromide Injection	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure)
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb

15.2. US State Regulations

Hydrochloric acid (7647-01-0)	
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
Sodium hydroxide (1310-73-2)	
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	

15.3. Canadian Regulations

Hydrochloric acid (7647-01-0)	
Listed on the Canadian DSL (Domestic Substances List)	

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Sodium hydroxide (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 10/02/2025

Revision

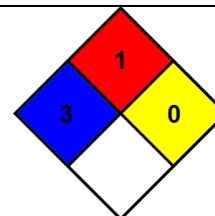
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2022-272.

GHS Full Text Phrases:	
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H361	Suspected of damaging fertility or the unborn child
H370	Causes damage to organs (Neuromuscular system).
H401	Toxic to aquatic life
H402	Harmful to aquatic life

NFPA Health Hazard : 3 - Materials that, under emergency conditions, can cause serious or permanent injury.

NFPA Fire Hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given

* Chronic - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 1 Slight Hazard

Physical : 0 Minimal Hazard

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC_RAR: European Commission Renewal Assessment Report

EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports

ECHA_API: European Chemicals Agency API

ECHA_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority

EPA: U.S. Environmental Protection Agency

EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)

EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA_HPVC: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU_CLH: European Union Harmonised Classification and Labelling Proposal

EU_RAR: European Union Risk Assessment Report

FOOD_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN_GHS: Japan GHS Basis for Classification Data

JP_J-CHECK: Japan J-Check

KR_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)

NLM_CIP: National Library of Medicine ChemID plus database

NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ_CCID: New Zealand Chemical Classification and Information Database

OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)

OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)

WHO: World Health Organization

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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.

NA GHS SDS 2024 (Can, US)