



## SAFETY DATA SHEET

**Product Name: Rocuronium Bromide Injection**

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
<b>Emergency Telephone</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000
<b>Product Name</b>	Rocuronium Bromide Injection
<b>Synonyms</b>	1-[17 $\beta$ -(acetyloxy)-3 $\alpha$ -hydroxy-2 $\beta$ -(4-morpholinyl)-5-androstan-16 $\beta$ -yl]-1-(2-propenyl) pyrrolidinium bromide.

### 2. HAZARD(S) IDENTIFICATION

<b>Emergency Overview</b>	Rocuronium Bromide Injection is a solution containing rocuronium bromide, a competitive non-depolarizing neuromuscular blocking agent with a rapid to intermediate onset. It is used as an adjunct to general anesthesia to facilitate endotracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation. In the workplace, rocuronium bromide should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the neuromuscular system and the cardiovascular system.
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#### U.S. OSHA GHS Classification

<b>Physical Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified
<b>Health Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified

#### **Label Element(s)**

<b>Pictogram</b>	NA
<b>Signal Word</b>	NA
<b>Hazard Statement(s)</b>	NA
<b>Precautionary Statement(s)</b>	
<b>Prevention</b>	Do not breathe vapor or spray Wash hands thoroughly after handling
<b>Response</b>	Get medical attention if you feel unwell.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** Rocuronium Bromide  
**Chemical Formula** C<sub>32</sub>H<sub>53</sub>BrN<sub>2</sub>O<sub>4</sub>

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Rocuronium Bromide	1	119302-91-9	NA

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium acetate and sodium chloride; acetic acid and/or sodium hydroxide are added to adjust the pH of the solution.

### 4. FIRST AID MEASURES

**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.

**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.

**Inhalation** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**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).

### 5. FIRE FIGHTING MEASURES

**Flammability** None anticipated for this aqueous product.

**Fire & Explosion Hazard** None anticipated for this aqueous product.

**Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

**Special Fire Fighting Procedures** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal** 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.

### 7. HANDLING AND STORAGE

**Handling** No special handling required under conditions of normal product use.

**Storage** No special storage required for hazard control. For product protection, follow the storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** No special precautions required for hazard control.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Rocuronium Bromide	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: Not established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

**Respiratory Protection**                      Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin Protection**                                If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**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.

**Engineering Controls**                        Engineering controls are normally not needed during the normal use of this product.

## 9. PHYSICAL/CHEMICAL PROPERTIES

<b>Appearance/Physical State</b>	A sterile, nonpyrogenic, isotonic solution that is clear, colorless to yellow/orange, for intravenous injection only
<b>Odor</b>	NA
<b>Odor Threshold</b>	NA
<b>pH</b>	4.0 (3.8-4.2)
<b>Melting point/Freezing Point</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Flash Point</b>	NA
<b>Evaporation Rate</b>	NA
<b>Flammability (solid, gas)</b>	NA
<b>Upper/Lower Flammability or Explosive Limits</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Relative Density</b>	NA
<b>Solubility</b>	Freely soluble in water and in dehydrated alcohol
<b>Partition Coefficient: n-octanol/water</b>	0.5 at 20°C
<b>Auto-ignition Temperature</b>	NA
<b>Decomposition Temperature</b>	NA
<b>Viscosity</b>	NA

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions. Store in airtight containers.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to Avoid</b>	Not determined
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), and hydrogen bromide (HBr).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity** - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Rocuronium Bromide	100	LD50	ND	ND	ND	ND

LD 50: Dosage that produces 50% mortality.

<b>Occupational Exposure Potential</b>	Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact with solution.
<b>Signs and Symptoms</b>	None anticipated from normal handling of this product. In clinical use, adverse effects may include hypotension, nausea and vomiting, irregular heart rate, tachycardia. The incidence of severe cardiovascular or allergic reactions is low. At high doses, rocuronium can cause respiratory paralysis. Rarely, hypersensitivity reactions such as rashes, wheezing, flushing, and shortness of breath have been reported.
<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/ Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/ Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation with redness and discomfort.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. Although rare, severe anaphylactic reactions to neuromuscular blocking agents, including rocuronium bromide, have been reported. These reactions have, in some cases, been life threatening.
<b>Reproductive Effects</b>	None anticipated from normal handling of this product. The effect of rocuronium bromide on fertility has not been evaluated in animal studies. Developmental toxicity studies were conducted in pregnant, conscious, non-ventilated rabbits and rats. The maximum tolerated dose, the high dose, was administered intravenously three times a day to rats (0.3 mg/kg) from day 6 to 17 and to rabbits (0.02 mg/kg) from day 6 to 18 of pregnancy. High-dose treatment caused acute symptoms of respiratory dysfunction due to the pharmacological activity of the drug. Teratogenicity was not observed in these studies. The incidence of late embryonic death was increased at the high-dose in rats and was most likely due to anoxia.

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Mutagenicity</b>	Rocuronium bromide was not mutagenic in a battery of genotoxicity studies (Ames test, analysis of chromosomal aberrations in mammalian cells, and micronucleus test).		
<b>Carcinogenicity</b>	The carcinogenic potential of rocuronium bromide has not been fully evaluated in long-term studies in animals.		
<b>Carcinogen Lists</b>	<b>IARC:</b> Not listed	<b>NTP:</b> Not listed	<b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA		
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs include the neuromuscular system and the cardiovascular system.		

**12 ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity</b>	Not determined for product.
<b>Persistence/ Biodegradability</b>	Not determined for product.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

Notes:

**13. DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

**14. TRANSPORTATION INFORMATION**

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

**15. REGULATORY INFORMATION**

<b>US TSCA Status</b>	Exempt
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**GHS/CLP Classification\***      \*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

<b>Hazard Class</b>	<b>Hazard Category</b>	<b>Pictogram</b>	<b>Signal Word</b>	<b>Hazard Statement</b>
NA	NA	NA	NA	NA
<b>Prevention</b>	Do not breathe vapor or spray Wash hands thoroughly after handling			
<b>Response</b>	Get medical attention if you feel unwell.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.			

**EU Classification\***      \*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

<b>Classification(s)</b>	NA
<b>Symbol</b>	NA
<b>Indication of Danger</b>	NA
<b>Risk Phrases</b>	NA
<b>Safety Phrases</b>	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

**16. OTHER INFORMATION**

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD <sub>50</sub>	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS  
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