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### Section 1 - Identification


- (a) **Product Identifier:** Rocuronium Bromide Injection
- (b) **Product Code:** 70860-651
- Common/Trade Name:** Rocuronium, Zemuron, Esmeron
- Chemical Name:** 1-[17β-(acetyloxy)-3α-hydroxy-2β-(4-morpholinyl)-5α-androstan-16β-yl]-1-(2-propenyl)pyrrolidinium bromide
- Chemical Family:** Muscle Relaxant, Paralytic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

### Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Not Classified

**(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**

<b>GHS Signal Word:</b>	N/A
<b>GHS Hazard Statement:</b>	N/A
<b>GHS Symbols:</b>	N/A

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<b>GHS Precautionary Statements:</b>	<p><b>Prevention:</b></p> <ul style="list-style-type: none"> <li>▪ Do not breathe vapor or spray</li> <li>▪ Wash hands thoroughly after handling</li> </ul> <p><b>Response:</b></p> <ul style="list-style-type: none"> <li>▪ Get medical attention if you feel unwell.</li> <li>▪ 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.</li> </ul>
<b>Other Hazards</b>	N/A


(d) Unknown Acute Toxicity N/A

### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
1-[17β-(acetyloxy)-3α-hydroxy-2β-(4-morpholinyl)-5α-androstan-16β-yl]-1-(2-propenyl)pyrrolidinium bromide	Rocuronium Bromide	10.0 mg/mL*	119302-91-9	N/A
Sodium Acetate trihydrate	Sodium Acetate trihydrate	2.0 mg/mL	6131-90-4	N/A
Sodium Chloride	Sodium Chloride	3.10 mg/mL	7647-14-5	N/A
Glacial Acetic Acid	Acetic Acid	**	64-19-7	N/A
Sodium Hydroxide	Sodium Hydroxide	**	1310-73-2	N/A
Water for Injection	Water	q.s. to 1 mL	7732-18-5	N/A
Nitrogen	Nitrogen	As required	7727-37-9	N/A

\*Assay correction to be done on as is basis.

\*\* q.s. to adjust pH.

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q.s. – quantity sufficient


#### Section 4 – First Aid Measures

<b>Eye Exposure:</b>	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.
<b>Skin Exposure:</b>	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
<b>Ingestion:</b>	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).
<b>Injection:</b>	In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
<b>Inhalation:</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Notes to Physician:</b>	Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

#### Section 5 – Fire-fighting Measures

- |  |   |
|--|---|
| (a) <b>Extinguishing Media</b>                         | As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.        |
| (b) <b>Hazardous Combustion Products:</b>              | None anticipated for this aqueous product   |
| (c) <b>Special Protective Equipment / Precautions:</b> | No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus. |

#### Section 6 - Accidental Release Measures

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**Spill:** 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.

**Release to Air:** No known information established.

**Release to Water:** Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

**Section 7 - Handling and Storage**

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

**Storage Conditions:** Rocuronium Bromide Injection should be stored in a refrigerator, 2° to 8°C (36° to 46°F). DO NOT FREEZE. Upon removal from refrigeration to room temperature storage conditions (25°C/77°F), use rocuronium bromide within 60 days. Use opened vials of rocuronium bromide within 30 days.

**Section 8 - Exposure Controls / Personal Protection**

**(a) Exposure Limits**


There is no specific work exposure limit for Rocuronium Bromide Injection.

Compound	Issuer	Type	Exposure Limit
Rocuronium Bromide	OSHA	PEL	NE
	ACGIH	TWA	NE

**(b) Engineering Controls**

There is no specific work exposure limit for Rocuronium Bromide Injection.


**(c) Individual Protection Measures**

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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.
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 Protection:	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Other Protective Equipment:	None
Additional Exposure Precautions:	None

**Section 9 - Physical and Chemical Properties**

<b>(a)</b>	<b>Appearance</b>	Clear, colorless to yellow/orange aqueous solution
<b>(b)</b>	<b>Odor</b>	No odor
<b>(c)</b>	<b>Odor Threshold</b>	Not available
<b>(d)</b>	<b>pH</b>	4.0
<b>(e)</b>	<b>Melting Point:</b>	Not available
<b>(f)</b>	<b>Initial Boiling Point:</b>	Not available
<b>(g)</b>	<b>Flash Point</b>	Not available
<b>(h)</b>	<b>Evaporation Rate:</b>	Not available
<b>(i)</b>	<b>Flammability</b>	Not available

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<b>(j)</b>	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
<b>(k)</b>	<b>Vapor Pressure:</b>	Not available
<b>(l)</b>	<b>Vapor Density:</b>	Not available
<b>(m)</b>	<b>Relative Density</b>	Not available
<b>(n)</b>	<b>Solubility(ies)</b>	Freely soluble in water and in dehydrated alcohol
<b>(o)</b>	<b>Partition Coefficient: n-octanol/water</b>	0.5 at 20°C
<b>(p)</b>	<b>Auto-ignition Temperature</b>	Not available
<b>(q)</b>	<b>Decomposition Temperature</b>	Not available
<b>(r)</b>	<b>Viscosity</b>	Not available

**Section 10 - Stability and Reactivity**

<b>(a)</b>	<b>Reactivity</b>	Not determined
<b>(b)</b>	<b>Chemical Stability</b>	Stable at normal temperature and pressures.
<b>(c)</b>	<b>Possibility of Hazardous Reactions</b>	Not determined
<b>(d)</b>	<b>Conditions to Avoid</b>	Not determined
<b>(e)</b>	<b>Incompatible Materials</b>	Not determined
<b>(f)</b>	<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).

**Section 11 - Toxicological Information**

<b>(a)</b>	<b>Likely Routes of Exposure</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.
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<b>(b)</b>	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Rocuronium Bromide Injection contains 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 possibly irritating to the eyes and respiratory tract. Possible target organs include the neuromuscular system and the cardiovascular system.
<b>(c)</b>	<b>Delayed and immediate effects and chronic effects from short and long term exposure</b>	<p>No signs or symptoms from occupational exposure are known. In clinical use, adverse effects may include hypotension, nausea and vomiting, irregular heart rate, tachycardia, and rarely, hypersensitivity reactions such as rashes, wheezing, flushing, and shortness of breath. The incidence of severe cardiovascular or allergic reactions is low. At high doses, rocuronium can cause respiratory paralysis.</p> <p>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.</p>

**(d) Acute Toxicity**

Not determined for the product formulation. Information for the active ingredient is as follows:

<b>Component</b>	<b>Type</b>	<b>Route</b>	<b>Species</b>	<b>Dosage</b>
Rocuronium Bromide	LD <sub>50</sub>	Oral	Rat	200-2,000 mg/kg

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Rocuronium Bromide	LD <sub>50</sub>	Intravenous	Rat	≈0.3 mg/kg
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**(e) Hazardous Chemical Listings**

**NTP:** Not Listed      **IARC:** Not Listed      **OSHA:** Not Listed      **ACGIH:** Not Listed

**Section 12 - Ecological Information**

<b>(a) Ecotoxicity</b>	Not Available.
<b>(b) Persistence and degradability</b>	Not Available.
<b>(c) Bioaccumulative potential</b>	Not Available
<b>(d) Mobility in soil</b>	Not available
<b>(e) Other Adverse Effects</b>	Not Available

**Section 13 - Disposal Considerations**


**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

**Section 14 - Transport Information**

**DOT:** Not regulated as a dangerous good.  
**IATA:** Not regulated as a dangerous good.  
**IMDG:** Not regulated as a dangerous good.

<b>(a) UN Number</b>	N/A
<b>(b) UN Proper Shipping Name</b>	N/A
<b>(c) Transport Hazard Class(es)</b>	N/A
<b>(d) Packing Group</b>	N/A
<b>(e) Environmental Hazards</b>	N/A
<b>(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	N/A
<b>(g) Special Precautions</b>	N/A



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### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**

- TSCA – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 311/312: Not on this list
- SARA 313 - Not on this list
- OSHA – Not on this list

### Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division  
 10 N. Martingale Road, Suite 230  
 Schaumburg, IL 60173  
 847-886-9515

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center

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DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

## Signature Manifest

**Document Number:** SDS018

**Revision:** 01

**Title:** Rocuronium Bromide Injection

All dates and times are in Eastern Standard Time.

**SDS018**

### Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	31 Aug 2017, 08:31:24 PM	Approved

### Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	12 Sep 2017, 12:02:44 PM	Approved

### Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	14 Sep 2017, 10:10:06 AM	Approved

### Review: SDS018 01 Rocuronium Bromide Injection

#### Review

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	15 Aug 2018, 12:08:04 PM	Reviewed
John Andre (JANDRE)	Regulatory Affairs Consultant	13 Sep 2018, 11:54:31 AM	Reviewed