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Section 1 - Identification


- (a) **Product Identifier:** Rocuronium Bromide Injection
- (b) **Product Code:** 25021-662
- Common/Trade Name:** Zemuron®
- Chemical Name:** 1-[17β-(acetyloxy)-3α-hydroxy-2β-(4-morpholinyl)-5α-androstan-16β-yl]-1-(2-propenyl)pyrrolidinium bromide
- Chemical Family:** Aminosteroid
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** **US OSHA:** Target Organ Toxin, Possible Irritant

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<p><u>GHS Precautionary Statements</u></p> <p>PREVENTION</p> <ul style="list-style-type: none"> - P260: Do not breathe dust/fume/gas/mist/vapors/spray <p>RESPONSE</p> <ul style="list-style-type: none"> - 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. Wash hands after handling - Call a POISON CENTER or doctor/physician if exposed or you feel unwell 	

- (d) **Unknown Acute Toxicity:** N/A


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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-[17 β -(acetyloxy)-3 α -hydroxy-2 β -(4-morpholinyl)-5 α -androstan-16 β -yl]-1-(2-propenyl)pyrrolidinium bromide	Rocuronium Bromide	1% (w/v)	119302-91-9	N/A
Sodium Chloride	Sodium Chloride	0.33% (w/v)	7647-14-5	N/A
Sodium Acetate Trihydrate	Sodium Acetate Trihydrate	0.2% (w/v)	6131-90-4	N/A
Water	Water for Injection	97.77% (w/v)	7732-18-5	N/A
Acetic Acid	Acetic Acid	0.7% (w/v)	64-19-7	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s to pH	1310-73-2	N/A

Section 4 - First Aid Measures

Eye Exposure:	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 Exposure:	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.
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).
Injection:	No information established.

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

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use extinguishing agent suitable for type of surrounding. Any water, carbon dioxide, Halon, foam, dry chemical or “ABC” class is acceptable.
- (b) **Hazardous Combustion Products:** No unusual or fire or explosion hazards are expected.
- (c) **Special Protective Equipment / Precautions:** No special provisions are required beyond fire-fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

Section 6 - Accidental Release Measures

Spill: For small releases of this product, wear latex or nitrile gloves and safety glasses.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways.


Release to Air: No known information established.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: As with all chemicals, avoid getting this product on you or in you. Do not eat, drink, smoke or apply cosmetics while handling this product. Wash hands thoroughly after handling.

Storage Conditions: Store refrigerated between 2°-8°C (36°-46°F). Upon removal from refrigeration to room temperature storage conditions (25°C /77°F), use Rocuronium Bromide Injection within 60 days. Use opened vials of Rocuronium Bromide Injection within 30 days.

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Rocuronium Bromide	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE


(b) Engineering Controls

Ventilation: Use with adequate ventilation. Follow standard medical product handling procedures.

(c) Individual Protection Measures

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. 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:	No special body protection required for routine, medical administration of this product. Wear lab coat, gown or smock, as appropriate for procedure. Use latex, nitrile or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.
Other Protective Equipment:	Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.
Additional Exposure Precautions:	None established


Section 9 - Physical and Chemical Properties

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(a)	Appearance	Clear, colorless to yellow/orange
(b)	Odor	Vinegar odor
(c)	Odor Threshold	Not Available
(d)	pH	4
(e)	Melting Point:	Approx 0°C
(f)	Initial Boiling Point:	Approx 100°C
(g)	Flash Point	Not Available
(h)	Evaporation Rate:	Approx 1
(i)	Flammability	Not Available
(j)	Upper Lower Flammability or Explosion Limits	Not Available
(k)	Vapor Pressure:	Not Available
(l)	Vapor Density:	Not Available
(m)	Relative Density	Specific Gravity is approx. 1
(n)	Solubility(ies)	Freely soluble in water and dehydrated alcohol
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not available
(b)	Chemical Stability	Stable under normal conditions and handling
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	Not determined
(e)	Incompatible Materials	This product is generally compatible with other common materials in a medical facility. Contact with acids liberates very toxic gas.
(f)	Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen bromide (HBr)

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Eye/skin contact, inhalation and ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	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.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Rocuronium Bromide	LD ₅₀	Oral	Rat	200-2000 mg/kg
Rocuronium Bromide	LD ₅₀	Intravenous	Rat	Appox 0.3 mg/kg

(e) Hazardous Chemical Listings


NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	Not available
(b)	Persistence and degradability	Not available
(c)	Bioaccumulative potential	Not available
(d)	Mobility in soil	Not available

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(e)	Other Adverse Effects	Not available
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Section 13 - Disposal Considerations

All waste materials must be properly characterized by the waste generator. Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent 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 - No

CERCLA - Not on this list


SARA 302, 304, 313 - Not on this list

OSHA Substance Specific - No

California Safe Drinking Water and Toxic Enforcement Act: Not on this list

Section 16 - Other Information

As of the date of issuance, 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

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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:

Sagent Pharmaceuticals, Inc.


1901 N. Roselle Rd, Suite 700

Schaumburg, IL 60195

847-908-1600

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 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
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 Association
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

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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