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Section 1 - Chemical Product and Company

Distributor:


Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier:	Rocuronium Bromide Injection
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:	C ₃₂ H ₅₃ BrN ₂ O ₄
Product Use:	Pharmaceutical
Product Type:	Regulated Prescription Drug
Container Information:	Vials

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Rocuronium Bromide	1	119302-91-9
Sodium Chloride	0.33	7647-14-5
Sodium Acetate Trihydrate	0.2	6131-90-4
Water for Injection	97.77	7732-18-5
Acetic Acid	0.7	64-19-7
Sodium Hydroxide	q.s to pH	1310-73-2

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Section 3 - Hazards Identification

Primary Physical and Health Hazards:

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.

Routes of Entry:

Eye/skin contact, inhalation and ingestion

Signs & Symptoms of 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.

Chemical Listed as Carcinogen:

NTP: No IARC: No OSHA: No

Medical Conditions Generally Aggravated by Exposure:

Hypersensitivity to rocuronium bromide or similar materials, or to other ingredients in this product; pre-existing neuromuscular or cardiovascular ailments.


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.

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- 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.
- 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

- Flash Point:** Not established
- Auto-ignition Temperature:** Not established
- Flammable Limits in Air:** Lower %: Not established
Upper %: Not established
- Flammable Limits:** Not established
- Extinguishing Media:** Use extinguishing agent suitable for type of surrounding. Any water, carbon dioxide, Halon, foam, dry chemical or "ABC" class is acceptable.
- Special Fire Fighting Procedures:** No special provisions are required beyond fire-fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.
- Unusual Fire/Explosion Hazards:** No unusual or fire or explosion hazards are expected.

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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.

Waste Disposal Method: 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.

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.

Section 8 - Exposure Controls / Personal Protection

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.

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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.

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

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

Exposure Limits


<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Rocuronium Bromide	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Isotonic solution	Specific Gravity:	Approx. 1
Appearance and Odor:	Clear, colorless to yellow/orange, Vinegar odor	Evaporation Rate:	Approx. 1
Boiling Point:	Approx. 100°C	Melting Point:	Not applicable
Vapor Pressure:	Not Available	Solubility in Water:	Soluble
Vapor Density:	Not Available	pH:	4
		Molecular Weight:	609.70

Section 10 - Stability and Reactivity

Stability: Stable under normal conditions and handling

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Incompatibility (Materials to avoid): This product is generally compatible with other common materials in a medical facility. Contact with acids liberates very toxic gas.

Hazardous Decomposition: 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)

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Not determined

Section 11 - Toxicological Information

Signs & Symptoms of 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.

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

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

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

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Section 14 - Transport Information

Regulatory Organizations:

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 MATERIAL 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:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
 847-908-1600

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

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
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
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
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
NIOSH	National Institute for Occupational Safety and Health
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
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)