

## Safety Data Sheet

**Rocuronium Bromide Injection****Section 1: Chemical Product and Company Identification****Product Name:** Rocuronium Bromide Injection**Chemical Name(s):** 1-[17 $\beta$ -(acetyloxy)-3 $\alpha$ -hydroxy-2 $\beta$ -(morpholin-4-yl)-5 $\alpha$ -androstan-16 $\beta$ -yl]-1-(prop-2-enyl) pyrrolidinium bromide**Synonym:** Not available**CAS Number:** 119302-91-9**RTECS #:** Not available**Trade Name:** Zemuron**Chemical Formula:**  $C_{32}H_{53}BrN_2O_4$ **Contact Information:**

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

**Technical Assistance:** 607-562-2700**Online Assistance:** [www.x-gen.us](http://www.x-gen.us)**Emergency phone number:**

National Poison Control

1-800-222-1222



Health	1
Fire	1
Reactivity	0
Personal Protection	E

\*\*For information regarding recommended uses and restrictions on usage refer to the product package insert.

**Section 2: Hazard Identification****Hazard pictograms (GHS-US):**

**Potential Acute Health Effects:** The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as paralysis with risk for respiratory failure and regurgitation of stomach contents due to relaxation of esophageal muscles, apnea resistant to neostigmine and atropine and in rare cases, histamine release with related effects may occur. Anaphylactic reactions to neuromuscular blocking agents in general have been reported.

**Potential Chronic Health Effects:** Not available

**Carcinogenic Effects:** Not available.

**Mutagenic Effects:** Studies did not suggest mutagenic potential.

**Teratogenic Effects:** Not observed in both rat and rabbit studies of Rocuronium Bromide. The incidence of late embryonic death was increased at the high-dose in rats most likely due to oxygen deficiency. Therefore, this finding probably has no relevance for humans because immediate mechanical ventilation of the intubated patient will effectively prevent embryo-fetal hypoxia. However, there are no adequate and well-controlled studies in pregnant women.

**Developmental Toxicity:** No studies on the reproductive toxicity potential of this product in laboratory animals were identified.

**Adverse effects:** Possible allergic reactions

### Section 3: Composition and Information on Ingredients

**Principle Components:**

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Rocuronium Bromide	119302-91-9	1
Sodium Chloride	7647-14-5	0.33
Acetic Acid	64-19-7	0.7
Sodium Acetate Trihydrate	6131-90-4	0.2
Water for Injection	7732-18-5	97.77

### Section 4: First Aid Measures

**General:** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

**Inhalation:** Remove from source of exposure. Provide symptomatic/supportive care as necessary. Seek medical attention immediately.

**Skin contact:** Remove contaminated shoes and clothing and cleanse affected areas thoroughly by washing with mild soap and water. Seek medical attention immediately.

**Eye contact:** Move victim away from exposure and into fresh air. If irritation or redness develops, flush eyes with clean water and seek medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 15 minutes. Seek medical attention immediately.

**Ingestion:** If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on left side with head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing. Seek medical attention immediately.

**Notes to physician:** Seek product package insert for complete information.

**Overdose Treatment:** Neostigmine and atropine must be ready for instant use. Treat overdose symptomatically.

## Section 5: Fire Fighting Measures

**Flammability of the product:** Non-flammable

**Combustion Products:** Not available.

**Unusual Fire and Explosion Hazards:** No unusual fire or explosion hazards are expected.

**Extinguishing Media and Instruction:** Use extinguishing agent suitable for type of surroundings. Any water, carbon dioxide, Halon, foam, dry chemical or “ABC” class is acceptable.

**Protective equipment & precautions for firefighters:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

**Special remarks on fire hazard:** Not available

**Special remarks on explosion hazard:** Not available

## Section 6: Accidental Release Measures

**Release to land:**

**Small spill:** Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

**Large Spill:** Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

**Release to air:** Not available

**Release to water:** Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways.

**Protective equipment:** Keep unnecessary personnel away. Wear approved respiratory protection, chemically compatible gloves and protective clothing such as protective coveralls and shoe covers for spills.

## Section 7: Handling and Storage

**Handling:** As a general rule, when handling Rocuronium Bromide Injection, avoid all contact and inhalation of mists and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. DO NOT ingest. DO NOT breathe dust. Wear suitable protective clothing. As with all chemicals, avoid getting this product in you or on you. Do not eat, drink, smoke or apply cosmetics while handling this product. Wash hands thoroughly after handling. Use only in accordance with directions.

**Storage:** Store refrigerated between 2° and 8°C (36° to 46°F). Upon removal from refrigeration to room temperature storage conditions, use Rocuronium Bromide Injection within 60 days. Use opened vials within 30 days. Refer to label instructions to ensure product integrity.

**Incompatibilities:** Not available

## Section 8: Exposure Controls / Personal Protection

**Engineering controls:** Use with adequate ventilation. Follow standard medical product handling procedures.

**Personal protection:** Safety glasses. Lab coat. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent. **In case of large spill:** Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

**Respiratory protection:** Not normally required for routine, medical administration of this product. . If dusts are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Exposure limit:** Not available

## Section 9: Physical and Chemical Properties

**Physical appearance:** Isotonic solution

**Color:** Colorless

**Molecular Weight:** 609.68

**Taste:** Not available

**Odor:** Odorless to almost odorless

**Odor Threshold:** Not available

**pH:** 4

**Melting Point:** Approx. 0°C

**Freezing Point:** Approx. 0°C

**Boiling Point:** Approx. 100°C

**Flash Point:** Not available

**Evaporation rate:** Not available

**Flammability:** Not available

**Upper Flammable Limit:** Not available

**Lower Flammable Limit:** Not available

**Vapor Pressure:** Not available

**Vapor Density:** Not available  
**Relative density:** Not available  
**Partition Coefficient:** Not available  
**Auto-Ignition Temperature:** Not available

**Decomposition Temperature:** Not available  
**Viscosity:** Not available  
**Dispersion Properties:** Not available  
**Solubility:** Completely soluble in water

## Section 10: Stability and Reactivity

**Reactivity:** Not available

**Chemical stability:** The product is stable under normal conditions and handling

**Possibility of hazardous reaction:** Not available

**Conditions to avoid:** not available

**Incompatible materials:** Contact with acids liberates very toxic gas.

**Hazardous decomposition products:** Heat may cause product to decompose, destroying the product or producing toxic fumes

**Corrosivity:** Non-corrosive in presence of glass.

**Polymerization:** Will not occur.

## Section 11: Toxicological Information

**Routes of exposure:** Inhalation, ingestion, skin and eye contact.

### Symptoms:

**Short term:** The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as paralysis with risk for respiratory failure and regurgitation of stomach contents due to relaxation of esophageal muscles, apnea resistant to neostigmine and atropine and in rare cases, histamine release with related effects may occur. Anaphylactic reactions to neuromuscular blocking agents in general have been reported. **Long term:** Not available

**Reproductive toxicity:** No studies on the reproductive toxicity potential of this product in laboratory animals were identified.

**FDA Pregnancy Category:** C

### Toxicity to animals:

**Oral Rat:** LD50: 200 - 2000 mg/kg

**IV Rat:** LD50: Approx. 0.3mg/kg

**Measures of toxicity:** Not available

**Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).**

### Section 12: Ecological Information

**Ecotoxicity:** No specific information is available on the effect of this product on plants and animals in the environment.

**Bioaccumulation potential:** Not available

**Products of biodegradation:** Not available

**Toxicity of the products of biodegradation:** Not available.

### Section 13: Disposal Information

**Waste classification:** Not available

**Waste from residues/unused products:** All waste materials must be properly characterized by the waste generator. Dispose of waste in accordance with all applicable federal, state and local laws.

**Waste Disposal:** All waste materials must be properly characterized by the waste generator. Dispose of waste in accordance with all applicable federal, state and local laws.

### Section 14: Transport Information

**DOT Classification:** Not available (United States).

**UN Number:** Not available

**UN Shipping name:** Not available

**Transport hazard class:** Not available

**Packing Group:** Not available

**Environmental hazard:** Not available

**Transport in bulk:** Not available

**Special precautions needed with transport:** Not available

### Section 15: Regulatory Information

**Federal and State Regulations:** TSCA 8(b) inventory: None

**Other Regulations:** OSHA: not available

**Other Classifications:**

**WHMIS (Canada):** Not available

**DSCL (EEC):** not available

**HMIS (U.S.A.):**

**Health Hazard:** 1

**Fire Hazard:** 1

**Reactivity:** 0

**Personal Protection:** E

**National Fire Protection Association (U.S.A.):**

**Health:** 1

**Flammability:** 1

**Reactivity:** 0

**Protective Equipment:** Gloves. Lab coat. Safety glasses. Dust Respirator. Be sure to use an approved/certified respirator or equivalent.

<b>Section 16: Other Information</b>
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**References:** Not available

**Created:** 1/30/2015

**Last Updated:** 3/27/2015

**Prepared & Approved by:** X-GEN Pharmaceuticals, Inc., Safety Committee

*The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.*