MATERIAL SAFETY DATA SHEET

Product Name: Rocuronium Bromide Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency 224-212-2000

Product Name Rocuronium Bromide Injection

Synonyms 1-[17ß-(acetyloxy)-3α-hydroxy-2ß-(4-morpholinyl)-5-androstan-16ß-yl]-1-(2-propenyl) pyrrolidinium bromide.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Rocuronium Bromide

Chemical Formula C_{32}H_{53}BrN_{2}O_{4}

Preparation 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.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>1</td>
<td>119302-91-9</td>
<td>NA</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview 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.

Occupational Exposure Potential 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.

Signs and Symptoms No signs or symptoms from occupational exposure are known. In clinical use, adverse effects may include hypotension, nausea and vomiting, irregular heart rate, tachycardia. The incidence
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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.

Medical Conditions Aggravated by Exposure

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

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. 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).

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.

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 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>mg/m3  ppm  µg/m3 Note</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>N/A  N/A  N/A None Established</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear, colorless to yellow/orange</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>4.0 (3.8-4.2)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or</td>
<td>NA</td>
</tr>
<tr>
<td>Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined

Chemical Stability
Stable under standard use and storage conditions. Store in airtight containers.

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Not determined

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).

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>100%</td>
<td>LD50</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent eye contact with this product may produce irritation with redness and discomfort.

Dermal or Respiratory Sensitization
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.

Reproductive Effects
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
Product Name: Rocuronium Bromide Injection

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.

Mutagenicity
Rocuronium bromide was not mutagenic in a battery of genotoxicity studies (Ames test, analysis of chromosomal aberrations in mammalian cells, and micronucleus test).

Carcinogenicity
The carcinogenic potential of rocuronium bromide has not been fully evaluated in long-term studies in animals.

Target Organ Effects
This material should be considered potentially irritating to the eyes and respiratory tract. Following an accidental over-exposure, possible target organs include the neuromuscular system and the cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product

Persistence/Biodegradability
Not determined for product

Bioaccumulation
Not determined for product

Mobility in Soil
Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal
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.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:
Not regulated

IMDG STATUS:
Not regulated

ICAO/IATA STATUS:
Not regulated

Transport Comments:
None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
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</table>
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**RCRA Status**  Not Listed

**U.S. OSHA Classification**  Target Organ Toxin

**Possible Irritant**

**GHS 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:

**Hazard Class**  Not Applicable

**Hazard Category**  Not Applicable

**Signal Word**  Not Applicable

**Symbol**  Not Applicable

**Prevention**  P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**Hazard Statement**  Not Applicable

**Response:**  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.

**EU Classification**

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Rocuronium Bromide.

**Classification(s):**  Not Applicable

**Symbol:**  Not Applicable

**Indication of Danger:**  Not Applicable

**Risk Phrases:**  R00 - Not Applicable

**Safety Phrases:**  S23 - Do not breathe vapor.

S24 - Avoid contact with skin.

S25 - Avoid contact with eyes.

S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

**Notes:**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
</tbody>
</table>
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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
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/19/2012
Obsolete Date: 11/03/2011

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