SAFETY DATA SHEET

Rocuronium Bromide Formulation

Section 1: Identification

Product name: Rocuronium Bromide Formulation

Manufacturer or supplier's details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

Section 2: Hazard identification

GHS Classification

Specific target organ toxicity - single exposure: Category 1 (Nervous system, muscle)

GHS label elements

Hazard pictograms: 

Signal word: Danger
Hazard statements: H370 Causes damage to organs (Nervous system, muscle).
Precautionary statements:

Prevention:
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
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Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>119302-91-9</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : 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.

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Causes damage to organs.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing method : Use extinguishing measures that are appropriate to local cir-
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Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe mist or vapours.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rocuronium Bromide</td>
<td>119302-91-9</td>
<td>TLV-C</td>
<td>5 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

#### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

#### Personal protective equipment

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **Filter type**: Particulates type

**Hand protection**

- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**Eye protection**

- **Remarks**: Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**

- **Remarks**: Work uniform or laboratory coat.
  - Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
  - Use appropriate degowning techniques to remove potentially
contaminated clothing.

Section 9: Physical and chemical properties

Appearance: suspension
Colour: colourless
Odour: odourless
Odour Threshold: No data available
pH: 5 - 8 (20 °C)
Melting point/freezing point: No data available
Initial boiling point and boiling range: 100 °C
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: Not applicable

Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: Can react with strong oxidizing agents.

Conditions to avoid: None known.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:

Acute oral toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Acute inhalation toxicity:
- Acute toxicity estimate: > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Acute dermal toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Components:

Rocuronium Bromide:

Acute oral toxicity:
- LD50 (Rat): 2,000 mg/kg
- LD50 (Rat): 200 mg/kg

Acute inhalation toxicity:
- LC50 (Rat, female): 0.63 mg/l
  Exposure time: 1 h
  Test atmosphere: dust/mist
  Remarks: Based on data from similar materials
  LC50 (Rat, male): 0.638 mg/l
  Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

LC50 (Rat, female): 0.368 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

LC50 (Rat): 1.09 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity: Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement

Acute toxicity (other routes of administration): LD50 (Rat): 0.3 mg/kg
Application Route: Intravenous

LD50 (Dog): 135 mg/kg
Application Route: Intravenous
Target Organs: Cardiovascular, Heart

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Rocuronium Bromide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative
Genotoxicity in vivo  :  Test Type: Micronucleus test  
   Species: Rat  
   Cell type: Bone marrow  
   Result: negative  

Carcinogenicity  
Not classified based on available information.  

Reproductive toxicity  
Not classified based on available information.  

Components:  
Rocuronium Bromide:  
Effects on foetal development  :  Test Type: Development  
   Species: Rat  
   Application Route: Intravenous  
   Developmental Toxicity: NOAEL: 0.05 mg/kg body weight  
   Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses  

   Test Type: Development  
   Species: Rat  
   Application Route: Intravenous  
   Developmental Toxicity: LOAEL: 0.3 mg/kg body weight  
   Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses  

   Test Type: Development  
   Species: Rabbit  
   Application Route: Intravenous  
   Developmental Toxicity: NOAEL: 0.02 mg/kg body weight  
   Result: No adverse effects, No effects on foetal development  

Reproductive toxicity - Assessment  :  Suspected of damaging the unborn child.  

STOT - single exposure  
Causes damage to organs (Nervous system, muscle).  

Product:  
Target Organs  :  Nervous system, muscle  
Assessment  :  Shown to produce significant health effects in animals at concentrations of 1.0 mg/l/4h or less.  

Components:  
Rocuronium Bromide:  
Target Organs  :  Nervous system, muscle  
Assessment  :  Causes damage to organs.  

STOT - repeated exposure  
Not classified based on available information.
Repeated dose toxicity

Components:

Rocuronium Bromide:
Species : Cat
NOAEL : 2.5 - 12.5 mg/kg
Application Route : Intravenous
Remarks : No significant adverse effects were reported

Species : Cat
LOAEL : 10.8 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks
Remarks : No significant adverse effects were reported

Species : Dog
LOAEL : 18 mg/kg
Application Route : Intravenous
Exposure time : 4 Weeks
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 1.3 - 2.6 mg/kg
Application Route : Subcutaneous
Exposure time : 1 Weeks
Remarks : No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Product:
Inhalation : Symptoms: The most common side effects are:, Cardiac arrhythmias, Gastrointestinal disturbance, Asthma, Rash, pruritis, Weakness, paralysis, hypertension, hypotension, Fatigue

Components:
Rocuronium Bromide:
Inhalation : Symptoms: The most common side effects are:, Cardiac arrhythmias, Gastrointestinal disturbance, Asthma, Rash, pruritis, Weakness, paralysis, hypertension, hypotension, Fatigue

Skin contact : Remarks: May produce an allergic reaction.

Section 12: Ecological information

Ecotoxicity
No data available

Persistence and degradability
No data available
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Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable

IATA-DGR
UN/ID No.: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Packing instruction (cargo aircraft): Not applicable
Packing instruction (passenger aircraft): Not applicable

IMDG-Code
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
EmS Code: Not applicable
Marine pollutant: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
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Version 3.5
Revision Date: 27.08.2021
SDS Number: 421891-00012
Date of last issue: 09.04.2021
Date of first issue: 05.01.2016

NZS 5433
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Hazchem Code: Not applicable

Special precautions for user
Not applicable

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NZ / EN