SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Rocuronium Bromide Formulation

Version 3.7  Revision Date: 27.08.2021  SDS Number: 439158-00014  Date of last issue: 09.04.2021

Date of first issue: 05.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Rocuronium Bromide Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Piercetown
   A86 HD21
   Dunboyne, Ireland
   Telephone : 908-740-4000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - single exposure, Category 1, Nervous system, muscle
   H370: Causes damage to organs.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H370 Causes damage to organs (Nervous system, muscle).
   Precautionary statements : Prevention:
   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
Rocuronium Bromide Formulation

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rocuronium Bromide</td>
<td>119302-91-9</td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2; H330</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H312</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rep. 2; H361d</td>
<td></td>
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<td></td>
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<td></td>
<td>STOT SE 1; H370</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(Nervous system, muscle)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute toxicity estimate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute dermal toxicity:</td>
<td>1,100 mg/kg</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes damage to organs.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
                                         Use personal protective equipment.
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Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- bent. 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>

8.2 Exposure controls

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.
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<tbody>
<tr>
<td>3.7</td>
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<td>439158-00014</td>
<td>09.04.2021</td>
</tr>
</tbody>
</table>

Personal protective equipment

Eye protection: 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.

Hand protection:

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

Skin and body protection:
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.

Respiratory protection:

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>colourless</td>
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<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>100 °C</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5 - 8 (20 °C)</td>
</tr>
</tbody>
</table>
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Viscosity
   Viscosity, kinematic : No data available

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water
   Vapour pressure : No data available

Relative density
   Density : No data available

Relative vapour density
   Particle characteristics
      Particle size : Not applicable

9.2 Other information
   Explosives : Not explosive
   Oxidizing properties : The substance or mixture is not classified as oxidizing.
   Evaporation rate : No data available
   Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
   Not classified as a reactivity hazard.

10.2 Chemical stability
   Stable under normal conditions.

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

10.4 Conditions to avoid
   Conditions to avoid : None known.

10.5 Incompatible materials
   Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
   No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure:
- 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): 0.368 mg/l
  Exposure time: 4 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
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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.

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
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Date of last issue: 09.04.2021
Date of first issue: 05.01.2016

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available
**12.5 Results of PBT and vPvB assessment**

**Product:**

**Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Endocrine disrupting properties**

**Product:**

**Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**12.7 Other adverse effects**

No data available

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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**

**14.1 UN number or ID number**

Not regulated as a dangerous good

**14.2 UN proper shipping name**

Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

Not regulated as a dangerous good

**14.4 Packing group**

Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Maritime transport in bulk according to IMO instruments**
SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable


<table>
<thead>
<tr>
<th>STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>H3 STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE</td>
<td>50 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

- H302: Harmful if swallowed.
- H312: Harmful in contact with skin.
H330 : Fatal if inhaled.
H361d : Suspected of damaging the unborn child.
H370 : Causes damage to organs.

Full text of other abbreviations

- Acute Tox. : Acute toxicity
- Repr. : Reproductive toxicity
- STOT SE : Specific target organ toxicity - single exposure

Further information

Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

<table>
<thead>
<tr>
<th>STOT SE 1</th>
<th>H370</th>
</tr>
</thead>
</table>

Classification procedure:

- Based on product data or assessment

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.

IE / EN