SAFETY DATA SHEET

Rocuronium Bromide Formulation

Version: 3.5  Revision Date: 09.04.2021  SDS Number: 421894-00012  Date of last issue: 23.03.2020  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
117 16th Road
1685 Halfway house, Midrand, South Africa

Telephone: +27 11 655 3000

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 CENTER/doctor.
SAFETY DATA SHEET

Rocuronium Bromide Formulation

Storage:
P405 Store locked up.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
</tr>
<tr>
<td>Rocuronium Bromide</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.

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 contain-
ment 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 absor-
bent.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to deter-
mine 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 as-
sessment
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 contami-
nated 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: Keep in properly labelled containers. Store locked up. Store in
areas and containers 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></td>
<td>Wipe limit</td>
<td>50 µg/100 cm²</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.

**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.

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Skin and body protection**

**Material**: 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 expo-
sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
- **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.

9.2 Other information
SAFETY DATA SHEET

Rocuronium Bromide Formulation

Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : Not applicable

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 toxicological effects
Information on likely routes of exposure : Inhalation
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.

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:
SAFETY DATA SHEET

Rocuronium Bromide Formulation

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 arrythmias, Gastrointestinal disturbance, Asthma, Rash, pruritis, Weakness, paralysis, hypertension, hypotension, Fatigue
rhythmias, 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 Other adverse effects

Product: Endocrine disrupting potential : 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 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
Not regulated as a dangerous good
SAFETY DATA SHEET

Rocuronium Bromide Formulation

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 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation;
SAFETY DATA SHEET

Rocuronium Bromide Formulation

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Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -
Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada);
ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Con-
centration associated with x% response; ELx - Loading rate associated with x% response; EmS -
Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concen-
tration associated with x% growth rate response; GHS - Globally Harmonized System; GLP -
Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - Inter-
national Air Transport Association; IBC - International Code for the Construction and Equipment of
Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO
- International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in
China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organi-
tzation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Stan-
ardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a
test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -
International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Speci-
fied; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse)
Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of
Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office
of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-
stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-
tative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European
Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Re-
striction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous
Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet;
SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA -
Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations
Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bio-
accumulative

Further information
Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD

Classification of the mixture:  
STOT SE 1  H370  Based on product data or assessment

The information provided in this Safety Data Sheet is correct to the best of our knowledge, infor-
mation 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 mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

ZA / EN