

Rocuronium Bromide Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 421875-00018 4.5 06.04.2024 Date of first issue: 05.01.2016

SECTION 1: IDENTIFICATION

Product name Rocuronium Bromide Formulation

Manufacturer or supplier's details

Company MSD

: Building A - Level 1/26 Talavera Rd Address

Macquarie Park NSW, Australia 2113

Telephone 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

single exposure

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

GHS label elements

Hazard pictograms

Signal word

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.



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Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Rocuronium Bromide	119302-91-9	>= 1 -< 3

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing : None known.



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media

Specific hazards during fire-

fighting

Hazardous combustion prod: :

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 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 deter-

mine 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.



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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 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Rocuronium Bromide	119302-91-9	TLV-C	4 μg/m3 (OEB 4)	Internal
		Wipe limit	40 μg/100 cm ²	Internal

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves



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Remarks : Consider double gloving.

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.

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, dis-

posable 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



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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 characteristics

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 reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : Oxidizing agents

Hazardous decomposition : No hazardous d

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



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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 toxicity estimate: 1,100 mg/kg Acute dermal toxicity

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.



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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 develop-

ment

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



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Application Route: Intravenous

Developmental Toxicity: NOAEL: 0.02 mg/kg body weight Result: No adverse effects, No effects on foetal development

Reproductive toxicity - As-

sessment

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 con-

centrations 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



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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Product:

Inhalation : Symptoms: The most common side effects are:, Cardiac ar-

rhythmias, Gastrointestinal disturbance, Asthma, Rash, pruritis, Weakness, paralysis, hypertension, hypotension, Fatique

Components:

Rocuronium Bromide:

Inhalation : Symptoms: The most common side effects are:, Cardiac ar-

rhythmias, 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

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 : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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



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Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

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 : Not applicable

circroft)

aircraft)

Packing instruction (passen-

ger 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 Not applicable **EmS Code** 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

ADG

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

Therapeutic Goods (Poisons:

Standard) Instrument

No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or

threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements

There is no applicable prohibition, authorisation and restricted use



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> requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

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

AICS not determined

DSL not determined

IECSC not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date 06.04.2024

Sources of key data used to

compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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 System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International 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 Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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 Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Trans-



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portation of Dangerous Goods; TECI - Thailand Existing Chemicals 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 Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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