

# **Rocuronium Bromide Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 30.09.2023 421889-00018 Date of first issue: 05.01.2016

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Rocuronium Bromide Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

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** 

Reproductive toxicity : Category 2

Specific target organ toxicity

- single exposure

Category 1 (Nervous system, muscle)

**GHS** label elements

Hazard pictograms

Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.

H370 Causes damage to organs (Nervous system, muscle).

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

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 dis-

posal plant.

#### Other hazards

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 -< 5	

## **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. 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

In case of eye contact

delayed

Protection of first-aiders

Suspected of damaging the unborn child. Causes damage to organs.

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 fire Exposure to combustion products may be a hazard to health.



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fighting

Hazardous combustion prod: :

ucts

Carbon oxides

Specific extinguishing meth-

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 fire-fighters

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

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency 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 diking or other appropriate

containment to keep material from spreading. If diked 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 vapors.

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



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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 labeled 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

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.



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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,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : suspension

Color : colorless

Odor : odorless

Odor 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n- : Not applicable



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octanol/water

Autoignition 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 reac- : Can react with strong oxidizing agents.

tions

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

Hazardous decomposition : No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

#### 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: > 5,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method



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**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 judgment

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.



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#### **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

Suspected of damaging the unborn child.

## Components:

#### **Rocuronium Bromide:**

Effects on fetal 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 fetal development.

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

## STOT-single exposure

Causes damage to organs (Nervous system, muscle).

#### **Product:**



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**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

10.8 mg/kg LOAEL 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

NOAEL 1.3 - 2.6 ma/ka 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 ar-

rhythmias, Gastrointestinal disturbance, Asthma, Rash, pruri-

tis, Weakness, paralysis, hypertension, hypotension, Fatigue

**Components:** 

**Rocuronium Bromide:** 



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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

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## **SECTION 14. TRANSPORT INFORMATION**

#### **International Regulations**

**UNRTDG** 

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable



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#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

## The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 30.09.2023 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 - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-



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mendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material 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/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8