

# **Rocuronium Bromide Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 9.0 2024/09/28 421887-00019 Date of first issue: 2016/01/05

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Rocuronium Bromide Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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

single exposure

**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:



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P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

#### 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.

## 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)



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Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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.



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#### 7. HANDLING AND STORAGE

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.

Avoidance of contact : Oxidizing agents

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.

**Storage** 

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

Packaging material : Unsuitable material: None known.

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

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



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**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

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state suspension

Colour colourless

Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

100 °C

Not applicable Flammability (solid, gas)

Flammability (liquids) No data available



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Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

No data available Decomposition temperature

5 - 8 (20 °C) pΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

No data available Viscosity, kinematic

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure No data available

Density and / or relative density

No data available Relative density

No data available Density

Relative vapour density 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

## 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.



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

Hazardous decomposition

products

: No hazardous decomposition products are known.

## 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: > 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



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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.



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#### 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

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



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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 ar-

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

# 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.

# 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

## Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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.

## 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

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

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**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



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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**

Refer to section 15 for specific national regulation.

## Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

## **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

# **Industrial Safety and Health Law**

### **Harmful Substances Prohibited from Manufacture**

Not applicable

### **Harmful Substances Required Permission for Manufacture**

Not applicable

## **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

# **Substances Subject to be Notified Names**

Not applicable

## **Substances Subject to be Indicated Names**

Not applicable

# Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

# Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable



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#### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

### Ordinance on Prevention of Lead Poisoning

Not applicable

# Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

## **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### Poisonous and Deleterious Substances Control Law

Not applicable

# Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

#### **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Not regulated as a dangerous good

#### **Aviation Law**

Not regulated as a dangerous good

#### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

## **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

# Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined



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#### 16. OTHER INFORMATION

#### **Further information**

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/

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

Date format : yyyy/mm/dd

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 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



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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.

JP / EN