

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	: Rocuronium Bromide Formulation (Caplin Steriles Ltd.)
Chemical Family	: 5alpha androstane
Synonyms	: 1-[17β-(acetyloxy)-3 α-hydroxy-2β-(4-morpholiny)-5 α-androstan-16β-yl]-1-(2-propenyl) pyrrolidinium bromide.
Manufacturer or supplier's details	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai,
Details of the Supplier of the Safety Data Sheet	: Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	: +91-4467901901/02/03
<u>Recommended use of the chemical and restrictions on use</u>	
Recommended use	: Nondepolarizing neuromuscular blocking agent.
Restrictions on use	: Not applicable

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS -Classification	Not classified as hazardous
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Label elements

Signal word	Not Classified
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Hazard statements	Not classified in accordance with international standards for workplace safety.
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Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
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Note:	This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
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SAFETY DATA SHEET

Rocuronium Bromide Injection



Caplin Steriles Limited

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENT

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Acetic acid	64-19-7	200-580-7	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	Adjust to pH
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr. 1A (H314)	Adjust to pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Rocuronium Bromide	119302-91-9	Not Listed	Not Listed	1
Sodium acetate trihydrate	127-09-3	204-823-8	Not Listed	0.2
Sodium Chloride	7647-14-5	231-598-3	Not Listed	0.33
Water for injection	7732-18-5	231-791-2	Not Listed	Qs to 100%

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:	Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Most Important Symptoms and Effects, Both Acute and Delayed	
Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media: As for primary cause of fire

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Formation of toxic gases is possible during heating or fire.

Products:

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

Incompatible Materials:	None known
Specific end use(s):	Pharmaceutical drug product

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

ACETIC ACID

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m ³
Australia TWA	10 ppm
	25 mg/m ³
Austria OEL - MAKs	10 ppm
	25 mg/m ³
Belgium OEL - TWA	10 ppm
	25 mg/m ³
Bulgaria OEL - TWA	25.0 mg/m ³
Cyprus OEL - TWA	10 ppm
	25 mg/m ³
Czech Republic OEL - TWA	25 mg/m ³
Denmark OEL - TWA	10 ppm
	25 mg/m ³
Estonia OEL - TWA	10 ppm
	25 mg/m ³
Finland OEL - TWA	5 ppm
	13 mg/m ³
Germany - TRGS 900 - TWAs	10 ppm
	25 mg/m ³
Germany (DFG) - MAK	10 ppm
	25 mg/m ³
Greece OEL - TWA	10 ppm
	25 mg/m ³
Hungary OEL - TWA	25 mg/m ³
Ireland OEL - TWAs	10 ppm
	25 mg/m ³
Latvia OEL - TWA	10 ppm
	25 mg/m ³
Lithuania OEL - TWA	10 ppm

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

	25 mg/m ³
Luxembourg OEL - TWA	10 ppm
	25 mg/m ³
Malta OEL - TWA	10 ppm
	25 mg/m ³
Netherlands OEL - TWA	25 mg/m ³
OSHA - Final PELs - TWAs:	10 ppm
	25 mg/m ³
Poland OEL - TWA	25 mg/m ³
Portugal OEL - TWA	10 ppm
	25 mg/m ³
Romania OEL - TWA	10 ppm
	25 mg/m ³
Slovakia OEL - TWA	10 ppm
	25 mg/m ³
Slovenia OEL - TWA	10 ppm
	25 mg/m ³
Spain OEL - TWA	10 ppm
	25 mg/m ³
Sweden OEL - TWAs	5 ppm
	13 mg/m ³
Switzerland OEL - TWAs	10 ppm
	25 mg/m ³
Vietnam OEL - TWAs	25 mg/m ³
SODIUM CHLORIDE	5 mg/m ³
Latvia OEL - TWA	
Lithuania OEL - TWA	5 mg/m ³
SODIUM HYDROXIDE	2 mg/m ³
ACGIH Ceiling Threshold Limit:	
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Bulgaria OEL - TWA	2.0 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELs - TWAs:	2 mg/m ³

SAFETY DATA SHEET

Rocuronium Bromide Injection



Caplin Steriles Limited

Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL -TWAs	2 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Rocuronium Bromide

Caplin Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Sodium Chloride

Caplin Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium Acetate

Caplin Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

standards in accordance with EN374, ASTM F1001 or international equivalent.)

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Eyes:

Skin:

Respiratory protection:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State:	Liquid
Color	Colourless to Yellow orange
Odor Threshold:	No data available.
Molecular Weight:	Mixture
Odor:	No data available.
Molecular Formula:	Mixture
Solvent Solubility:	No data available
Water Solubility:	Soluble
pH:	3.8-4.2
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

SODIUM CHLORIDE

No data available

Water for Injection

No data available

ACETIC ACID

No data available

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

SODIUM HYDROXIDE

No data available

Sodium Acetate

No data available

Rocuronium Bromide

No data available

Decomposition Temperature

(°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: None

Conditions to Avoid: None known

Incompatible Materials: None known

Hazardous Decomposition Products: Thermal decomposition products include oxides of nitrogen, carbon monoxide, carbon dioxide, and halogen containing gases.

SECTION 11: TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include increase in blood pressure (hypertension), nausea, vomiting,

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

irregular heartbeat (cardiac arrhythmia), increased heart rate (tachycardia),
respiratory arrest, troubled breathing.

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³

Rat Oral LD 50 3g/kg

Mouse Oral LD 50 4g/kg

Rabbit Dermal LD 50 > 10g/kg

ACETIC ACID

Mouse Sub-tenon injection (eye) LC 50 5620 ppm/1H

Rat Oral LD 50 3310mg/kg⁹

Rabbit Dermal LD 50 1060uL/kg

Sodium Acetate

Rat Oral LD 50 3500 mg/kg

Mouse Oral LD 50 4960mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Rocuronium Bromide

Embryo / Fetal Development Rat Intravenous 0.3 mg/kg NOAEL Not teratogenic

Embryo / Fetal Development Rabbit Intravenous 0.02 mg/kg NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Rocuronium Bromide

Bacterial Mutagenicity (Ames) Negative

Chromosome Aberration Negative

Micronucleus Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

ACETIC ACID

Fathead Minnow	NPDES	LC-50	96 Hours	88 mg/L
Bluegill Sunfish	NPDES	LC-50	96 Hours	75 mg/L
Goldfish	NPDES	LC-50	24 Hours	423 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15: REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 2
for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	200-580-7

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

EU EINECS/ELINCS List	231-598-3
SODIUM ACETATE	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8
SODIUM HYDROXIDE	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances	1000 lb
and their Reportable Quantities:	454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 5
for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	215-185-5
WATER FOR INJECTION	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the	Present
obligations of Register:	
EU EINECS/ELINCS List	231-791-2

SECTION 16: OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

SDS creation date : Dec 07, 2024

SDS Revision date : NA

Version # : 00

Disclaimer: To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

SAFETY DATA SHEET
Rocuronium Bromide Injection



Caplin Steriles Limited

---End of Safety Data Sheet---