SAFETY DATA SHEET

Rocuronium Bromide Injection

1) PRODUCT AND COMPANY IDENTIFICATION

Product name: Rocuronium Bromide Injection

Synonyms: N/A

CAS Number:

Rocuronium Bromide	119302-91-9
Sodium Acetate Trihydrate	6131-90-4
Sodium Chloride	7647-14-5
Water for Injection	7732-18-5

Formula: N/A

Chemical Family: N/A

Recommended Use: **N/A**

Manufacturer:
Sanovel
Sanayi ve Ticaret Anonim Sirketi,
Istinye Mahallesi Balabandere
Caddesi No. 14, 34460,
Sanyer, Istanbul, Turkey
General Phone Number: 90 212 362 18 00

Supplier:
Piramal Critical Care, Inc.
3950 Schelden Circle
Bethlehem, PA 18017
Customer Service Phone Number: 800-414-1901
24 Hour Emergency Number: CHEMTREC 1-703-527-3887
E-Mail: pcccustomerconnect@piramal.com

2) HAZARDS IDENTIFICATION

Classification of Substance / Mixture:
GHS – Classification Not classified as hazardous

Label Elements:
Signal Word – Not Classified
Hazard Statements – Not Classified
Precautionary Statements – Not Classified

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdose are described in the package insert.

Route of Exposure: Inhalation, Ingestion, Eye Contact, Skin Absorption, Injection

Potential Health Effects:

Eye: Contact with eyes may cause irritation

Skin: May cause skin irritation

Inhalation: May cause irritation of respiratory tract

Ingestion: May cause irritation

Signs/Symptoms: Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses may include: possible adverse reactions include: Arrhythmia, tachycardia, nausea, vomiting, bronchospasm, wheezing, rash, pruritus. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with a hypersensitivity to rocuronium bromide

3) COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS #	Ingredient Percent
Rocuronium Bromide	119302-91-9	10 m g/m l
Sodium Acetate Trihydrate	6131-90-4	2 m g/m 1
Sodium Chloride	7647-14-5	- for isotonicity –
Water for Injection	7732-18-5	- quantity sufficient -

4) FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15-20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Note to Physician: An antagonist (such as neostigmine, edrophonium) in conjunction with an appropriate anticholinergic agent can be given once evidence of recovery from the neuromuscular block is observed

5) FIRE FIGHTING MEASURES

Flammable Properties: Combustible

Flash Point: Not established

Flash Point Method: Not established

Auto Ignition Temperature: Not established

Lower Flammable/Explosive Limit: Not established

Upper Flammable/Explosive Limit: Not established

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, container fire run-off water.

Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

6) ACCIDENTAL RELEASE MEASURES

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches or waterways.

Methods for Containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for Cleanup: Absorb spill with inert materials (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

7) HANDLING AND STORAGE

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage: Store at refrigerated temperatures 2 to 8ºC (36 to 46ºF). Protect from freezing.

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet/fume hood to control airborne levels below recommended exposure limits.

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exists.

Skin Protection: Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection: Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection: No personal respiratory protective equipment is normally required when this product is being used/ administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician/doctor/nurse for its sold intended parenteral (injection purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH website (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.

Other Protective: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Exposure Guidelines

Ingredient	Guideline OSHA	Guideline ACGIH
Rocuronium Bromide	Not established.	Not established.
Sodium Acetate Trihydrate	Not established.	Not established.
Sodium Chloride	Not established.	Not established.
Water for Injection	Not established.	Not established.

9) PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Color: Clear to yellow
Boiling Point: Not established
Melting Point: Not established
Solubility: No data
Vapor Density: Not established
Vapor Pressure: Not established
Percent Volatile: Not established.
pH: 4.0
Molecular Formula: Mixture
Molecular Weight: 609.70
Flash Point: Not established
Flash Point Method: Not established
Auto Ignition Temperature: Not established

10) STABILITY AND REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures
Hazardous Polymerization: Not reported.
Conditions to Avoid: No conditions contributing to instability are known to exist for normal handling of this product

11) TOXICOLOGICAL INFORMATION

Reproductive Toxicity: Pregnancy Category C: Rocuronium caused acute symptoms of respiratory dysfunction in rabbits and rats. Teratogenicity was not observed in these animal species. There are no adequate and well-controlled studies in pregnant women. Rocuronium Bromide Injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Rocuronium Bromide**:**

Ingestion:	Oral – Mouse LD50:20 gm/kg Oral – Rat LD50: 200 mg/kg
Other Toxicological Information:	LD50 IV Rat: >150 mcg/kg LD50 IV Mouse: 50 mcg/kg LD50 SC Rat: 400 mcg/kg LD50 SC Mouse: 150 mcg/kg

Sodium Chloride:

RTECS Number:	VZ4725000
Eye:	Eye – Rabbit Standard Draize test: 100 mg/24H Eye – Rabbit Standard Draize test: 10 mg (RTECS)
Skin:	Administration onto the skin – Rabbit LD50: >10 gm/kg [details of toxic effects not reported other than lethal dose value] Administration onto the skin – Rabbit Standard Draize test: 50 mg/24H [mild] Administration onto the skin – Rabbit Standard Draize test: 500mg/24H [mild]
Ingestion:	Oral – Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral – Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intravenous – Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal – Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal – Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous – Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]

12) ECOLOGICAL INFORMATION

Ecotoxicity Effects:	No ecotoxicity data was found for the product
Environmental Stability:	No environmental information found for this product.

13) DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial Regulations

14) TRANSPORT INFORMATION

DOT shipping name:	Not regulated
UN number:	Not regulated

15) REGULATORY INFORMATION

Canada WHMIS:	Controlled – Class: D2B Toxic

16) OTHER INFORMATION

HMIS Ratings:
HMIS Health Hazard: 1

HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	x

Piramal provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. PIRAMAL MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, PIRAMAL WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

SDS Updates:
04-14-2019 – New Document