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Vecuronium Bromide for Injection

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Vecuronium Bromide for Injection

Synonyms: Vecuronium Bromide for Injection, 10 mg; Vecuronium Bromide for Injection, 20 mg

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information. Restricted to professional users.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317, USA
+1.724.514.1800

Contact e-mail:

SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:

For Hazardous Materials Incident
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC (24 Hours)
Worldwide: +1 703-741-5970

Other Contact Information

FDA Adverse Events Reporting Number:

For reporting adverse health events call:
+1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Classification

Skin corrosion/irritation, Category 2

Serious eye damage/eye irritation, Category 2A

Specific target organ toxicity (single exposure), Category 1 (Respiratory system)

Label elements



Signal word:

Danger

Hazard statements:

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H370 - Causes damage to organs

Precautionary Statements - Prevention:	Do not breathe dust/fume/gas/mist/vapors/spray Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Wear protective gloves/eye protection/face protection
Precautionary Statements - Response:	IF exposed: Call a POISON CENTER or doctor Specific treatment (see supplemental first aid instructions on this label)
Eyes:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention
Skin:	IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse
Precautionary Statements - Storage:	Store locked up
Precautionary Statements - Disposal:	Dispose of contents/container to an approved waste disposal plant
Other Hazards	No information available.
Unknown acute toxicity	No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Chemical name	CAS No.	Weight-%	Hazard statements
Citric Acid	77-92-9	10 - 20%	H315 - Causes skin irritation H319 - Causes serious eye irritation
Vecuronium bromide	50700-72-6	5 - 10%	H302 - Harmful if swallowed H370 - Causes damage to organs

4. FIRST AID MEASURES

Description of first aid measures

Overdose: Signs and symptoms of excessive exposure may be dyspnea and cessation of breathing.

General advice: Never give anything by mouth to an unconscious person, IF exposed or concerned: Get medical advice/attention, Show this safety data sheet to the doctor in attendance

Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur. Artificial respiration and/or oxygen may be necessary. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Skin contact: Wash off immediately with soap and plenty of water for at least 15 minutes. If symptoms persist, call a physician.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.

Remove contact lenses, if present and easy to do. Continue rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Ingestion: Do not induce vomiting without medical advice. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention immediately if symptoms occur.

Self-protection of the first aider: Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms: Difficulty in breathing. Respiration insufficiency.

Inhalation: May cause cardiac and respiratory depression.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. If not breathing, give artificial respiration.

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical

Fire hazard: Not flammable.

Explosive hazard: Not an explosive. Dust can form an explosive mixture with air.

Reactivity: Hazardous reactions will not occur under normal conditions.

Hazardous combustion products: Carbon oxides. Nitrogen oxides. Hydrogen bromide.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.

Firefighting instructions: Use water spray or fog; do not use straight streams.

Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear

Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information. Restricted to professional users.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves. Impervious gloves.

Eye/face protection: If splashes are likely to occur, wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection: Use appropriate respiratory protection. Avoid breathing dust or spray mist. Use exhaust ventilation to keep airborne concentrations below exposure limits. In case of inadequate ventilation wear respiratory protection. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.

General hygiene considerations: Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Powder; Solid
Appearance:	crystalline powder
Color:	White to off-white
Odor:	No data available
Odor threshold:	No data available

pH:	3.5 - 4.5
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
VOC Content (%):	No data available

10. STABILITY AND REACTIVITY

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: Specific test data for the substance or mixture is not available. May be harmful if inhaled.

Ingestion: Specific test data for the substance or mixture is not available. May be harmful if swallowed.

Eye contact: Specific test data for the substance or mixture is not available. Contact with eyes may cause irritation. (based on components).

Skin contact: Specific test data for the substance or mixture is not available. May cause skin irritation. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Difficulty in breathing. Respiration insufficiency.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: Classification based on data available for ingredients. Irritating to skin.

Serious eye damage/eye irritation: Classification based on data available for ingredients. Irritating to eyes.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT - single exposure: Based on the classification criteria of the Globally Harmonized System as adopted in the country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity from acute exposure. (STOT SE). May cause damage to the following organs: Respiratory system.

STOT - repeated exposure: Based on available data, the classification criteria are not met

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION**Ecotoxicity**

No information available.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG**UN Number**

Not regulated

UN proper shipping name

Not regulated

Transport hazard class(es)

Hazard Class: Not regulated

Packing group

Not regulated

Environmental hazards

No

Special precautions for user

No information available

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

Not applicable

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations****Ozone-depleting substances (ODS):** Not applicable**Persistent Organic Pollutants:** Not applicable**The Rotterdam Convention:** Not applicable**US Federal Regulations**

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations: This product does not contain any substances regulated by state right-to-know regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sodium Phosphate Dibasic Anhydrous (CAS #: 7558-79-4)	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all

the information required by the CPR.

16. OTHER INFORMATION

Revision Date:	25-July-2017
Data Sources:	This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard CFR 1912.1200.
Other Information:	This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:**Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

Phone number: 304-559-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.

Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. 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 completeness of the information 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.

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