SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Vecuronium Bromide for Injection**
Manufacturer Name:	Gland Pharma Limited
Address:	Survey No.: 143 - 148, 150 & 151, Near Gandimaisamma Cross Roads D.P. Pally, Quthubullapur Mandal - Ranga Reddy District Hyderabad, Andhra Pradesh 500 043 India
General Phone Number:	+91-40-30510999
General Fax Number:	+91-40-30510810
Emergency Phone Number:	+91-40-30510999
Distributor Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 25, 2017
SDS Revision Date:	February 06, 2017

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Serious Eye Damage. category 1.
Skin Irritation. Category 2.
Acute Oral Toxicity. Category 4.

Hazard Statements:
H318 - Causes serious eye damage.
H315 - Causes skin irritation.
H302 - Harmful if swallowed.

Precautionary Statements:
P264 - Wash hands thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor/physician.
P321 - Specific treatment (see ... on this label).
P330 - Rinse mouth.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

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

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Acute Health Effects: Potentially irritating to the eyes and respiratory tract and a potent drug.

Eye: None anticipated from normal handling of this product. Dibasic sodium phosphate is reported to be a mild eye irritant while citric acid is reported to be a severe eye irritant. Inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Skin: None anticipated from normal handling of this product. Citric acid and dibasic sodium phosphate have been reported to be mild skin irritants. Inadvertent contact of this product with skin may produce mild irritation.

Signs/Symptoms: None anticipated from normal handling of this product. In clinical use, excessive doses of vecuronium may result in enhanced pharmacological effects. These effects may include skeletal muscle weakness, decreased respiratory reserve, low tidal volume, or apnea. Respiratory depression may be due either wholly or in part to other drugs used during the conduct of general anesthesia such as narcotics, thiobarbiturates and other central nervous system depressants. The administration of vecuronium has been associated with rare instances of hypersensitivity reactions (bronchospasm, hypotension and/or tachycardia, sometimes associated with acute urticaria or erythema).

Target Organs: Based on clinical use, possible target organs include the skeletal muscle, the nervous system and the respiratory system.

Aggravation of Pre-Existing Conditions: None anticipated from normal handling of this product. However, clinical use of this product has been associated with rare instances of hypersensitivity reactions.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Citric Acid	77-92-9	14 %	201-069-1
Mannitol	69-65-8	67 by weight	200-711-8
Sodium Phosphate, Dibasic	7558-79-4	11 by weight	231-448-7
Vecuronium Bromide	50700-72-6	7 by weight	256-723-9
Water for Injection	7732-18-5	Balance %	231-791-2

Notes : Sodium hydroxide and/or phosphoric acid may be use to adjust the pH.

SECTION 4 : FIRST AID MEASURES

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.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek 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.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

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, contain 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.

SECTION 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, and waterways.
Methods for containment:	For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water.
Methods for cleanup:	Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations.

SECTION 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:	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
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.

SECTION 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 exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	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 sole 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 web site (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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Crystalline powder.
Color:	Colorless.
Odor:	Not determined.
Boiling Point:	Not established.
Melting Point:	227-229°C
Specific Gravity:	Not established.
Solubility:	Not established.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.5-4.5
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Avoid contact with strong oxidizing agents.
Special Decomposition Products:	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen bromide (HBr).

SECTION 11 : TOXICOLOGICAL INFORMATION

Carcinogenicity:	The carcinogenic potential of this product has not been evaluated.
Mutagenicity:	The mutagenic potential of this product has not been evaluated.
Citric Acid :	
Eye:	Administration into the eye - Rabbit Standard Draize test: 750 ug/24H [Severe] (RTECS)
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50 - Lethal dose, 50 percent kill: 11700 mg/kg [Behavioral - Ataxia Cardiac - Change in rate Lungs, Thorax, or Respiration - Respiratory depression] (RTECS)
Mannitol :	
RTECS Number:	OP2060000
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 13500 mg/kg [Details of toxic effects not reported other

	than lethal dose value] (RTECS)
Other Toxicological Information:	Intravenous. - Rat LD50: 9690 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 7470 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 14 gm/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Phosphate, Dibasic :

RTECS Number:	WC4500000
Eye:	Administration into the eye - Rabbit Standard Draize test: 500 mg/24H [Mild] (RTECS)
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 17000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Vecuronium Bromide :

RTECS Number:	TN4875000
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 455 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Dyspnea] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

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

SECTION 13 : DISPOSAL CONSIDERATIONS

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

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Citric Acid :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	201-069-1

Mannitol :

TSCA Inventory Status:	Listed
EINECS Number:	200-711-8
Canada DSL:	Listed
EC Number:	200-711-8

Sodium Phosphate, Dibasic :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	231-448-7

Vecuronium Bromide :

Canada DSL:	Listed
EC Number:	256-723-9

Water for Injection :

EC Number:	231-791-2

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date: January 25, 2017

SDS Revision Date:	February 06, 2017
SDS Revision Notes:	"Update"
Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.