Conforms to HCS 2012 - United States

SAFETY DATA SHEET

Vecuronium Bromide for Injection, USP 10 mg/vial & 20 mg/vial

Section 1. Identification

GHS product identifier : Vecuronium Bromide for Injection, USP 10 mg/vial & 20 mg/vial

Product code : Not available.

Other means of identification : Not available.

Product type : Regulated pharmaceutical ingredient.

Container information : 10 R & 20 R vials.

Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Vecuronium bromide is indicated as an adjunct to general anesthesia, to facilitate endotrachealintubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Supplier's details : Hikma Pharmaceuticals USA Inc.
246 Industrial Way West
Eatontown, New Jersey (NJ) 07724

Emergency telephone number (with hours of operation) : CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887
24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H319 - Causes serious eye irritation.

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statements

Prevention : P280 - Wear eye or face protection.
P264 - Wash hands thoroughly after handling.

Response : P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 - If eye irritation persists: Get medical attention.

Storage : Not applicable.

Disposal : Not applicable.

Section 2. Hazards identification

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Not available.

Ingredient name	%	CAS number
Citric acid Disodium hydrogenorthophosphate Vecuronium bromide	10 - 30 10 - 30 5 - 10	77-92-9 7558-79-4 50700-72-6

Active pharmaceutical ingredient	%	CAS number
Vecuronium bromide	5 - 10	50700-72-6

The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

See Package Insert for further information.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes serious eye irritation.

Section 4. First aid measures

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
phosphorus oxides
halogenated compounds
metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Citric acid	None.
Disodium hydrogenorthophosphate	None.
Vecuronium bromide	None.

Section 8. Exposure controls/personal protection

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state : Lyophilized powder. [Freeze dried white to off white cake of very fine microscopic crystalline particles.]

Color : White to off white.

Odor : Not available.

Odor threshold : Not available.

pH : 3.5 to 4.5 [Conc. (% w/w): 1%]

Melting point : Not available.

Boiling point : Not available.

Flash point : Not applicable.

Evaporation rate : Not available.

Flammability (solid, gas) : Not applicable.

Lower and upper explosive (flammable) limits : Not applicable.

Section 9. Physical and chemical properties

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : Not available.

Solubility : Reconstituted time NMT 60 seconds. Constituted solution: no visible residue as undissolved matter. The constituted solution is not significantly less clear than an equal volume of the Purified water contained in a similar vessel and examined similarly.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not applicable.

Decomposition temperature : Not available.

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Citric acid	LD50 Oral	Rat	3 g/kg	-
Disodium hydrogenorthophosphate	LD50 Oral	Rat	17000 mg/kg	-
Vecuronium bromide	LD50 Oral	Rat	455 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Citric acid	Eyes - Severe irritant	Rabbit	-	24 hours 750 µg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
Disodium hydrogenorthophosphate	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Section 11. Toxicological information

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Section 11. Toxicological information

Acute toxicity estimates

Route	ATE value
Oral	4956 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Citric acid Disodium hydrogenorthophosphate	Acute LC50 160000 µg/L Marine water Acute LC50 3580000 µg/L Fresh water	Crustaceans - Carcinus maenas - Adult Daphnia - Daphnia magna	48 hours 48 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Citric acid Disodium hydrogenorthophosphate	-1.8 -5.8	- -	low low

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

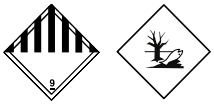
Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	UN3077	Not regulated.	Not regulated.
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Disodium hydrogenorthophosphate)	-	-

Section 14. Transport information

Transport hazard class(es)	9 	-	-
Packing group	III	-	-
Environmental hazards	Yes.	No.	No.

AERG : 171

DOT-RQ Details : Disodium hydrogenorthophosphate 5000 lbs / 2270 kg

Additional information

DOT Classification : Non-bulk packages of this product are not regulated as hazardous materials in package sizes less than the product reportable quantity, unless transported by inland waterway. The marine pollutant mark is not required when transported on inland waterways in sizes of ≤5 L or ≤5 kg.
Reportable quantity 44247.8 lbs / 20088.5 kg. Package sizes shipped in quantities less than the product reportable quantity are not subject to the RQ (reportable quantity) transportation requirements.

IATA : The environmentally hazardous substance mark may appear if required by other transportation regulations.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

FDA : Vecuronium Bromide for Injection, USP 10 mg/vial & 20 mg/vial is an approved prescription medication.

U.S. Federal regulations : **United States inventory (TSCA 8b)**: Not determined.
Clean Water Act (CWA) 311: Disodium hydrogenorthophosphate

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Section 15. Regulatory information

Classification : SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A

Composition/information on ingredients

Name	Classification
Citric acid	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A
Disodium hydrogenorthophosphate	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A
Vecuronium bromide	ACUTE TOXICITY (oral) - Category 4

SARA 313

There is no data available.

State regulations

Massachusetts : The following components are listed: Disodium hydrogenorthophosphate

New York : The following components are listed: Disodium hydrogenorthophosphate

New Jersey : The following components are listed: Disodium hydrogenorthophosphate

Pennsylvania : The following components are listed: Disodium hydrogenorthophosphate

California Prop. 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A	Calculation method

History

Date of issue mm/dd/yyyy : 03/30/2019

Date of previous issue : Not applicable

Version : 1

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

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