



SAFETY DATA SHEET

Revision date: 07-Mar-2019

Version: 2.1

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Vecuronium Bromide for Injection (Hospira Inc)

Trade Name: Not applicable

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for skeletal muscle relaxation

Details of the Supplier of the Safety Data Sheet

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Hazard Statements: May form combustible dust concentrations in air

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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3. COMPOSITION / INFORMATION ON INGREDIENTS

Vecuronium bromide	50700-72-6	256-723-9	Acute Tox. 4 (H302)	1 - 5
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
Phosphoric acid	7664-38-2	231-633-2	Skin Corr. 1B (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	*
Citric Acid	77-92-9	201-069-1	Not Listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

** to adjust 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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards:

Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. 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.

Specific end use(s): Pharmaceutical product used for skeletal muscle relaxation

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Vecuronium bromide

Pfizer OEL TWA-8 Hr: 60µg/m³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m ³
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
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Phosphoric acid

ACGIH Threshold Limit Value (TWA)	1 mg/m ³
ACGIH Threshold Limit Value (STEL)	3 mg/m ³
Australia STEL	3 mg/m ³
Australia TWA	1 mg/m ³
Austria OEL - MAKs	1 mg/m ³
Belgium OEL - TWA	1 mg/m ³
Bulgaria OEL - TWA	1.0 mg/m ³
Cyprus OEL - TWA	1 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
Denmark OEL - TWA	1 mg/m ³
Estonia OEL - TWA	1 mg/m ³
Finland OEL - TWA	1 mg/m ³
France OEL - TWA	0.2 ppm 1 mg/m ³
Germany - TRGS 900 - TWAs	2 mg/m ³
Germany (DFG) - MAK	2 mg/m ³
Greece OEL - TWA	1 mg/m ³
Hungary OEL - TWA	1 mg/m ³
Ireland OEL - TWAs	1 mg/m ³
Italy OEL - TWA	1 mg/m ³
Latvia OEL - TWA	1 mg/m ³
Lithuania OEL - TWA	1 mg/m ³
Luxembourg OEL - TWA	1 mg/m ³
Malta OEL - TWA	1 mg/m ³
Netherlands OEL - TWA	1 mg/m ³
OSHA - Final PELs - TWAs:	1 mg/m ³
Poland OEL - TWA	1 mg/m ³
Portugal OEL - TWA	1 mg/m ³
Romania OEL - TWA	1 mg/m ³
Slovakia OEL - TWA	1 mg/m ³
Slovenia OEL - TWA	1 mg/m ³
Spain OEL - TWA	1 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL -TWAs	1 mg/m ³
Vietnam OEL - TWAs	1 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.

Sodium phosphate, dibasic

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

Exposure Controls

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	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.)
Skin:	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.)
Respiratory protection:	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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	White to off-white
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Vecuronium bromide	No data available		
Mannitol	No data available		
Citric Acid	No data available		
Sodium phosphate, dibasic	No data available		
Water for injection	No data available		
SODIUM HYDROXIDE	No data available		
Phosphoric acid	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		

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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

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Short Term: Active ingredient may be harmful if swallowed.

Long Term: Repeated or prolonged exposure may cause effects similar to those seen in clinical use.

Known Clinical Effects: Drugs of this class may cause muscle weakness, respiratory depression.

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

Vecuronium bromide

Rat Oral LD50 455 mg/kg

Mouse Oral LD 50 41mg/kg

Rat Intravenous LD 50 0.20mg/kg

Mouse Intravenous LD 50 0.05mg/kg

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

Phosphoric acid

Rat Oral LD50 1530 mg/kg

Rabbit Dermal LD 50 2730mg/kg

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

Citric Acid

Eye Irritation Rabbit Irritant

Skin Irritation Rabbit Non-irritating

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11. TOXICOLOGICAL INFORMATION

Phosphoric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

Toxicity:

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

Phosphoric acid

Gambusia affinis (Mosquitofish) LC50 96 Hours 3-3.5 mg/L

Daphnia magna (Water Flea) EC-50 12 Hours 4.6 mg/L

Persistence and Degradability:

No data available

Bio-accumulative Potential:

No data available

Mobility in Soil:

No data available

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.

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.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Vecuronium bromide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	256-723-9

Mannitol

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 obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Citric Acid

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	201-069-1

Sodium phosphate, dibasic

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Phosphoric acid

CERCLA/SARA 313 Emission reporting	Not Listed
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15. REGULATORY INFORMATION

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
California Proposition 65	2270 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-633-2

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 obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 6 - Accidental Release Measures.

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet