SAFETY DATA SHEET

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

Revision date: 07-Mar-2019
Version: 2.1

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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>

PZ03166
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vecuronium bromide</td>
<td>50700-72-6</td>
<td>256-723-9</td>
<td>Acute Tox. 4 (H302)</td>
<td>1 - 5</td>
</tr>
<tr>
<td>SODIUM HYDROXIDE</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Phosphoric acid</td>
<td>7664-38-2</td>
<td>231-633-2</td>
<td>Skin Corr. 1B (H314)</td>
<td>**</td>
</tr>
</tbody>
</table>

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

PZ03166
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

<table>
<thead>
<tr>
<th>Measures for Cleaning / Collecting:</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Consideration for Large Spills:</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Storage Conditions:</th>
<th>Store as directed by product packaging.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific end use(s):</td>
<td>Pharmaceutical product used for skeletal muscle relaxation</td>
</tr>
</tbody>
</table>

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Vecuronium bromide

<table>
<thead>
<tr>
<th>Pfizer OEL TWA-8 Hr:</th>
<th>60µg/m³</th>
</tr>
</thead>
</table>

SODIUM HYDROXIDE

<table>
<thead>
<tr>
<th>ACGIH Ceiling Threshold Limit:</th>
<th>2 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Substance</th>
<th>OEL - TWAs</th>
<th>MAKs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slovenia</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Phosphoric acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>1.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Cyprus</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>0.2 ppm</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Luxembourg</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Malta</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td>1 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

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**
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Powder</td>
<td>Color</td>
<td>White to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Vecuronium bromide

Mannitol

Citric Acid

Sodium phosphate, dibasic

Water for injection

SODIUM HYDROXIDE

Phosphoric acid

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
Material Name: Vecuronium Bromide for Injection (Hospira Inc)
Revision date: 07-Mar-2019

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
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.
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
SAFETY DATA SHEET

Material Name: Vecuronium Bromide for Injection (Hospira Inc)
Revision date: 07-Mar-2019

Page 9 of 9

Version: 2.1

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity, oral</td>
<td>Cat. 4; H302 - Harmful if swallowed</td>
</tr>
<tr>
<td>Skin corrosion/irritation, skin</td>
<td>Cat. 1A; H314 - Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>Skin corrosion/irritation, eye</td>
<td>Cat. 1B</td>
</tr>
</tbody>
</table>

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.

Revision date: 07-Mar-2019
Prepared by: Product Stewardship Hazard Communication

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