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

Product Identifier

Material Name: Bivalirudin for Injection (Hospira Inc.)

Trade Name:
Bivalirudin for Injection

Chemical Family:
Mixture

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

Intended Use:
Pharmaceutical product used as anticoagulant agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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

Signal Word: Not required
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.
SAFETY DATA SHEET

Material Name: Bivalirudin for Injection (Hospira Inc.)
Revision date: 07-Mar-2019

3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

<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>Bivalirudin</td>
<td>128270-60-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>58</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>
</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:** Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash off immediately with soap and plenty of water. If irritation occurs or persists, get 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. May include oxides of carbon, nitrogen and products of fluorine.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.
Advice for Fire-Fighters
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 the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum 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). 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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Bivalirudin
Pfizer OEL TWA-8 Hr: 200 TWA; 1.5 STELµg/m³

SODIUM HYDROXIDE
ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK: 2 mg/m³
Austria OEL - MAKs: 2 mg/m³
Bulgaria OEL - TWA: 2.0 mg/m³
Czech Republic OEL - TWA: 1 mg/m³
Estonia OEL - TWA: 1 mg/m³
France OEL - TWA: 2 mg/m³
Greece OEL - TWA: 2 mg/m³
Hungary OEL - TWA: 2 mg/m³
Japan - OELs - Ceilings: 2 mg/m³
Latvia OEL - TWA: 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA: 0.5 mg/m³
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: Lyophilized powder
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 5-6 (reconstituted)
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value) Bivalirudin

No data available SODIUM HYDROXIDE
No data available Mannitol
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
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: May cause mild eye irritation.
Known Clinical Effects: Clinical use of this drug has caused hemorrhage, gastrointestinal bleeding, increased bleeding time. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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

Bivalirudin
- Rat Subcutaneous LD50 > 150 mg/kg
- Rabbit Subcutaneous LD50 > 150mg/kg

Mannitol
- Rat Oral LD 50 13500 mg/kg
- Mouse Oral LD 50 22 g/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Bivalirudin
- Fertility and Embryonic Development to the fetus: Rat Subcutaneous 150 mg/kg/day NOAEL No evidence of impaired fertility or harm
- Fertility and Embryonic Development harm to the fetus: Rabbit Subcutaneous 150 mg/kg/day NOAEL No evidence of impaired fertility or harm

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Bivalirudin

PZ03251
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11. TOXICOLOGICAL INFORMATION

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: No data available
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
15. REGULATORY INFORMATION

Bivalirudin

| 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               | Not Listed |

SODIUM HYDROXIDE

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances   | 1000 lb    |
| and their Reportable Quantities:   | 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 |
| EU EINECS/ELINCS List              | 215-185-5  |

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  |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; 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 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity.

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