



# SAFETY DATA SHEET

Revision date 22-Apr-2022

Version 3

Page 1 / 10

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Bivalirudin for Injection (Hospira Inc.)  
**Product Code(s)** PZ03251  
**Trade Name:** Bivalirudin for Injection  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as anticoagulant agent

### 1.3. 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

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

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887  
**E-mail address** pfizer-MSDS@pfizer.com

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

Not classified as hazardous

### 2.2. Label elements

**Signal word** Not classified

**Hazard statements** Not classified in accordance with international standards for workplace safety.

### 2.3. Other hazards

**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 require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 2 / 10  
Version 3

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

**Substances** Not applicable

### 3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Bivalirudin 128270-60-0	58		Not Listed	No data available	Not Listed	No data available	No data available
Sodium hydroxide 1310-73-2	**		215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Mannitol 69-65-8	*		200-711-8	No data available	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

#### Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available

#### 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. Non-hazardous ingredients provided for completeness.

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 3 / 10  
Version 3

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water. If irritation occurs or persists, get medical attention.
<b>Ingestion</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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### 4.3. Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray.
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### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the chemical</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Hazardous combustion products</b>	Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen and products of fluorine

### 5.3. Advice for firefighters

<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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### 6.3. Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
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# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 4 / 10  
Version 3

**Methods for cleaning up** 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.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Bivalirudin**

Pfizer OEL TWA-8 Hr: 200 TWA; 1500 STEL  $\mu\text{g}/\text{m}^3$

#### **Mannitol**

Russia MAC: 10  $\text{mg}/\text{m}^3$

#### **Sodium hydroxide**

ACGIH OEL (Ceiling) 2  $\text{mg}/\text{m}^3$

ACGIH TLV Ceiling: 2  $\text{mg}/\text{m}^3$

Austria 2  $\text{mg}/\text{m}^3$

STEL 4  $\text{mg}/\text{m}^3$

Bulgaria 2.0  $\text{mg}/\text{m}^3$

Czech Republic 1  $\text{mg}/\text{m}^3$

Ceiling: 2  $\text{mg}/\text{m}^3$

Denmark Ceiling: 2  $\text{mg}/\text{m}^3$

Estonia 1  $\text{mg}/\text{m}^3$

STEL: 2  $\text{mg}/\text{m}^3$

Finland Ceiling: 2  $\text{mg}/\text{m}^3$

France 2  $\text{mg}/\text{m}^3$

Hungary 1  $\text{mg}/\text{m}^3$

STEL: 2  $\text{mg}/\text{m}^3$

Ireland STEL: 2  $\text{mg}/\text{m}^3$

Ceiling Limit Value 2  $\text{mg}/\text{m}^3$

Latvia 0.5  $\text{mg}/\text{m}^3$

Poland STEL: 1  $\text{mg}/\text{m}^3$

0.5  $\text{mg}/\text{m}^3$

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 5 / 10  
Version 3

Romania	1 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup>
United Kingdom	(vacated) Ceiling: 2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup>

## 8.2. Exposure controls

<b>Engineering controls</b>	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.
<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	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.
<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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.).
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Lyophilized powder
<b>Color</b>	White
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

<u>Property</u>	<u>Values</u>
<b>pH</b>	5-6
<b>pH (as aqueous solution)</b>	(reconstituted)
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 6 / 10  
Version 3

<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	Soluble
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## **9.2. Other information**

No information available

### **9.2.1. Information with regard to physical hazard classes**

No information available

### **9.2.2. Other safety characteristics**

No information available

## **Section 10: STABILITY AND REACTIVITY**

### **10.1. Reactivity**

**Reactivity** No data available.

### **10.2. Chemical stability**

**Stability** Stable under normal conditions.

### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

### **10.4. Conditions to avoid**

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

### **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### **10.6. Hazardous decomposition products**

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### **11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 7 / 10  
Version 3

**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 > 150 mg/kg

### Mannitol

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

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Mannitol	= 13500 mg/kg ( Rat )	-	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-

**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.

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

### Bivalirudin

Skin Sensitization - GPMT Guinea Pig Negative

### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

## Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

### Bivalirudin

28 Day(s) Rat Continuous IV Infusion 25 mg/kg/day NOAEL Liver, Bone marrow, Spleen  
14 Day(s) Monkey Continuous IV Infusion 45 mg/kg/day NOAEL Heart

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

### Bivalirudin

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

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

### Bivalirudin

Bacterial Mutagenicity (Ames) Negative  
HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative  
*In Vitro* Unscheduled DNA Synthesis Rat Hepatocyte Negative  
*In Vivo* Micronucleus Rat Negative

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

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 8 / 10  
Version 3

**Endocrine disrupting properties** No information available.

**11.2.2. Other information**  
**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 wastewater 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.

## Section 14: TRANSPORT INFORMATION



# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 9 / 10  
Version 3

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Bivalirudin

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Mannitol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-711-8
AICS	Present

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

# SAFETY DATA SHEET

Product Name Bivalirudin for Injection (Hospira Inc.)  
Revision date 22-Apr-2022

Page 10 / 10  
Version 3

## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of H-Statements referred to under 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.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 22-Apr-2022

**Prepared By** Pfizer Global Environment, Health, and Safety

**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.**