


| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 1 of 8 |

Section 1 - Identification

- (a) **Product Identifier:** Bivalirudin for Injection
- (b) **Product Code:** 83634-400
- Common/Trade Name:** Bivalirudin for Injection
- Chemical Name:**
D-phenylalanyl-L-prolyl-Larginyl- L-prolyl-glycyl-glycyl-glycyl-glycyl-L-asparagyl-glycyl-L-aspartyl-L-phenylalanyl-L-glutamyl-Lglutamyl-L-isoleucyl-L-prolyl-L-glutamyl-L-glutamyl-L-tyrosyl-L-leucine.
- Chemical Family:** Anticoagulant Agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229


Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Not classified as hazardous

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

| | |
|--------------------------------------|-----|
| GHS Signal Word: | N/A |
| GHS Hazard Statement: | N/A |
| GHS Symbols: | N/A |
| GHS Precautionary Statements: | N/A |
| Other Hazards | N/A |

- (d) **Unknown Acute Toxicity** N/A

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 2 of 8 |


Section 3 – Composition / Information on Ingredients

| (a) Chemical Name | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|---|------------------------------|---|-------------|---|
| D-phenylalanyl-L-prolyl-L-arginyl-L-prolyl-glycyl-glycyl-glycyl-glycyl-L-asparagyl-glycyl-L-aspartyl-L-phenylalanyl-L-glutamyl-L-glutamyl-L-isoleucyl-L-prolyl-L-glutamyl-L-glutamyl-L-tyrosyl-L-leucine. | Bivalirudin | 250 mg/ vial | 128270-60-0 | N/A |
| Mannitol | Mannitol | 125 mg | 69-65-8 | N/A |
| Sodium Hydroxide | Sodium Hydroxide | q.s. to adjust pH to 5 to 6 | 1310-73-2 | N/A |

q.s. – Quantity Sufficient

Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes with water for at least 15 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Seek medical attention.
- Skin Exposure:** Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if irritation develops or persists.
- Ingestion:** Do not induce vomiting or give anything by mouth to an unconscious person. Flush mouth out with water immediately if conscious. Seek medical attention or call poison control center immediately.
- Inhalation:** Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) or oxygen by trained personnel if required. Seek immediate medical attention.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 3 of 8 |

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use water fog or spray, alcohol resistant foam or dry chemical extinguisher as appropriate for surrounding fire and materials.
- (b) **Hazardous Combustion Products:** Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion. .
- (c) **Special Protective Equipment / Precautions:** Evacuate area of unprotected personnel. Wear self-containing breathing apparatus and full protective gear. If possible, contain fire run-off water.

Section 6 - Accidental Release Measures

- Spill:** Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.
- Release to Air:** Minimize dust generation and accumulation; avoid breathing dust, vapors or mists. Non-essential personnel should be evacuation from the affected area.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage


- General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30° C (59° and 86° F). [See USP Controlled Room Temperature.]

Section 8 - Exposure Controls / Personal Protection

Engineering Controls

Ventilation: General room ventilation is satisfactory. Use local exhaust ventilation if necessary.

Individual Protection Measures

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 4 of 8 |


| | |
|----------------------------------|---|
| Respiratory Protection: | With satisfactory ventilation, respiratory protection is usually not required. |
| Eye Protection: | Safety glasses or goggles recommended. Wear a face shield also when splash hazard exists. |
| Skin Protection: | Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended. |
| Other Protective Equipment: | Protective laboratory coat, apron, or disposable garment recommended. |
| Additional Exposure Precautions: | Not established. |

Section 9 - Physical and Chemical Properties

| | | |
|-----|---|------------------------|
| (a) | Appearance | White lyophilized cake |
| (b) | Odor | Odorless |
| (c) | Odor Threshold | Not available |
| (d) | pH | 5 to 6 |
| (e) | Melting Point: | Not available |
| (f) | Initial Boiling Point: | Not available |
| (g) | Flash Point | Not available |
| (h) | Evaporation Rate: | Not available |
| (i) | Flammability | Not available |
| (j) | Upper Lower Flammability or Explosion Limits | Not available |
| (k) | Vapor Pressure: | Not available |
| (l) | Vapor Density: | Not available |
| (m) | Relative Density | Not available |
| (n) | Solubility(ies) | Soluble in water |
| (o) | Partition Coefficient: n-octanol/water | Not available |
| (p) | Auto-ignition Temperature | Not available |
| (q) | Decomposition Temperature | Not available |
| (r) | Viscosity | Not available |

Section 10 - Stability and Reactivity

| | | |
|-----|-------------------|----------------|
| (a) | Reactivity | Not determined |
|-----|-------------------|----------------|

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 5 of 8 |


| | | |
|------------|---|--|
| (b) | Chemical Stability | Stable under standard use and storage conditions. |
| (c) | Possibility of Hazardous Reactions | Hazardous polymerization has not been reported. |
| (d) | Conditions to Avoid | No conditions contributing to instability are known to exist |
| (e) | Incompatible Materials | Keep away from strong oxidizers as a precaution. |
| (f) | Hazardous Decomposition Products | Thermal decomposition products may include carbon monoxide, carbon dioxide and oxides of nitrogen. |

Section 11 - Toxicological Information

| | | |
|------------|--|--|
| (a) | Likely Routes of Exposure | Inhalation, eye/skin contact or ingestion |
| (b) | Symptoms related to the physical, chemical and toxicological characteristics | May cause mild eye irritation. |
| (c) | Delayed and immediate effects and chronic effects from short and long-term exposure | 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. |

(a) Acute Toxicity

| Component | Type | Route | Species | Dosage |
|------------------|------------------|-----------------|---------|--------------|
| Bivalirudin | LD ₅₀ | Subcutaneous | Rat | 150 mg/kg |
| | LD ₅₀ | Subcutaneous | Rabbit | 150 mg/kg |
| Mannitol | LD ₅₀ | Oral | Rat | 13,500 mg/kg |
| | LD ₅₀ | Oral | Mouse | 22 g/kg |
| | LD ₅₀ | Intravenous | Rat | 9690 mg/kg |
| | LD ₅₀ | Intravenous | Mouse | 7470 mg/kg |
| | LD ₅₀ | Intraperitoneal | Mouse | 14 g/kg |
| Sodium Hydroxide | LDLo | Oral | Rabbit | 500 mg/kg |

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 6 of 8 |

(b) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed

Section 12 - Ecological Information

| | | |
|------------|--------------------------------------|----------------------------|
| (a) | Ecotoxicity | Not determined for product |
| (b) | Persistence and degradability | Not determined for product |
| (c) | Bioaccumulative potential | Not determined for product |
| (d) | Mobility in soil | Not determined for product |
| (e) | Other Adverse Effects | Not determined for product |

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

| | | |
|------------|---|-----|
| (a) | UN Number | N/A |
| (b) | UN Proper Shipping Name | N/A |
| (c) | Transport Hazard Class(es) | N/A |
| (d) | Packing Group | N/A |
| (e) | Environmental Hazards | N/A |
| (f) | Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code) | N/A |
| (g) | Special Precautions | N/A |


Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not regulated

CERCLA - Not on this list

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 7 of 8 |

SARA 302 - Not on this list
SARA 311/312: Not on this list
SARA 313 - Not on this list
OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

| | |
|------------|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AICS | Australian Inventory of Chemical Substances |
| AIHA | American Industrial Hygiene Association |
| ANSI | American National Standards Institute |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| DSL | Domestic Substances List |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | Environmental Protection Agency |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals |
| HEPA | High Efficiency Particulate Air (Filter) |
| HMIS | Hazardous Materials Identification System |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |

| | | | | |
|---|--|----------------------------------|---------------------------|-----------------------|
|  | Document Type: Safety Data Sheet | Bivalirudin for Injection | | |
| | Effective Date: 25 OCT 2023 | SDS No.: SDS001 | Revision No: 01 | Page 8 of 8 |

| | |
|-------|---|
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NDSL | Non-Domestic Substances List |
| NFPA | National Fire Protection Association |
| NIOSH | National Institute for Occupational Safety and Health |
| NPDES | National Pollutant Discharge Elimination System |
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |
| WHMIS | Workplace Hazardous Materials Information System |