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Section 1 - Identification


- (a) **Product Identifier:** Bivalirudin for Injection
- (b) **Product Code:** 70860-402
- 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:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

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

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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-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.	Bivalirudin	250 mg/ vial	128270-60-0	N/A
Mannitol	Mannitol	125 mg/ vial	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.

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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

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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
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(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

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(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 Athenex Pharmaceutical Division 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

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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:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

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

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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

Signature Manifest

Document Number: SDS034

Revision: 01

Title: Bivalirudin for Injection

All dates and times are in Eastern Standard Time.

Bivalirudin for Inj SDS approval

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Emily Means (EMEANS)	QA Document Specialist	09 Oct 2019, 07:08:10 AM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	14 Oct 2019, 03:52:46 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	14 Oct 2019, 04:15:05 PM	Approved