



SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Bivalirudin Injection (5mg/mL)
- b) **Common/Trade Name** : Bivalirudin Injection(5mg/mL)
Chemical Names : D-phenylalanyl-L-prolyl-L-arginyl-L-prolyl-glycylglycyl-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
- Chemical Family** : Anticoagulant
- c) **Product Use** : Specific and reversible direct thrombin inhibitor; anticoagulant
- Product Type** : Regulated Prescription Drug
- Container Information** : Vial
- d) **Manufacturers Name & Address** : **Gland Pharma Limited**
: Survey No.: 143–148, 150&151
: Near Gandimaisamma Cross Roads,
: D.P.Pally, Quthubullapur Mandal
: Ranga Reddy District
: Hyderabad- 500043
: Telangana, India
- e) **Telephone Number for Info** : +91-40-30510999

SECTION 2 – HAZARDS IDENTIFICATION

a) **Classification**

NFPA Rating

Health Hazard : 2

Fire Hazard : 0

Reactivity Hazard : 0

b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	c) Description of Hazards:
Signal Word: Danger	-Not Available
Causes severe skin burns and eye damage, Causes serious eye damage May cause damage to organs through prolonged or repeated exposures	

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 Number	d) Impurities / Stabilizing Additives
D-phenylalanyl-L-prolyl-L-arginyl-L-prolyl-glycylglycyl-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	5 mg/mL	128270-60-0	N/A
Sodium acetate trihydrate	Sodium acetate trihydrate	0.8mg/mL	6131-90-4	N/A
Polyethylene Glycol 400	Polyethylene Glycol 400	100 mg/mL	25322-68-3	N/A
Sodium hydroxide	Sodium hydroxide	q.s for pH adjustment	1310-73-2	N/A
Acetic acid, Glacial	Glacial acetic acid	q.s for pH adjustment	64-19-7	N/A
Water	Water for Injection	q.s.to 1 mL	7732-18-5	N/A

SECTION 4 – FIRST AID MEASURES

- Eye Exposure** : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Skin Exposure** : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Ingestion** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary
- Injection** : NA
- Inhalation** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
- Notesto Physician** : See patient package insert in shipping carton for complete information



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SECTION 5 – FIRE FIGHTING MEASURES

- a) **Extinguishing Media** : As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
- b) **Hazardous Combustion Products** : None anticipated for this product. Avoid the generation of dusty environments.
- c) **Special Protective Equipment / Precautions** : No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus

SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Spill** : Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect powder using techniques that minimize the creation of airborne dust. Clean the area with soap and water. If the spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
- Release to Air** : NA
- Release to Water** : NA

SECTION 7 – HANDLING AND STORAGE

- General Handling** : Gloves, masks and goggles are recommended during handling.
- Storage Conditions** : Store at 2°C to 8°C (36°F to 46°F).



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SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Bivalirudin	OSHA ACGIH AIHA	PEL TLV WEEL	NE NE NE (8 hr TWA)
Sodium acetate trihydrate	NA	NA	NA
Polyethylene Glycol 400	AIHA	WEEL	10 (mg/m ³) TWA
Glacial acetic acid	ACGHI	TWA	(25 mg/m ³ TWA) TWA 15 ppm
Sodium hydroxide	OSHA ACGIH AIHA	PEL TLV WEEL	NE (2mg/m ³) NE (2mg/m ³ , Ceiling) NE (8 hr TWA)

b) Engineering Controls

Engineering controls are normally not needed during the normal use of this product

(c) Individual Protection Measures

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

Respiratory Protection :	Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Eye Protection :	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Skin Protection :	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.



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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

a)	Appearance/Description	:	A clear to slightly opalescent, colorless to yellow solution essentially free from visible particulates.
b)	Odor	:	NA
c)	Odor Threshold	:	NA
d)	pH	:	5.0-5.50
e)	Melting Point	:	NA
f)	Initial Boiling Point	:	NA
g)	Flash Point	:	NA
h)	Evaporation Rate	:	NA
i)	Flammability	:	NA
j)	Upper Lower Flammability or Explosion Limits	:	NA
k)	Vapor Pressure:	:	NA
l)	Vapor Density	:	NA
m)	Relative Density	:	NA
n)	Solubility(ies)	:	NA
o)	Partition Coefficient: n-octanol/water	:	NA
p)	Auto-ignition Temperature	:	NA
q)	Decomposition Temperature	:	NA
r)	Viscosity	:	NA

SECTION 10 – STABILITY AND REACTIVITY

a)	Reactivity	Not determined.
b)	Chemical Stability	Stable under normal use and storage conditions.
c)	Possibility of Hazardous Reactions	Not determined
d)	Conditions to Avoid	Strong acids and bases, excessive heat.
e)	Incompatible Materials	Not determined
f)	Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), and hydrogen fluoride.



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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	None known from occupational exposure. Inadvertent inhalation of the powder or aerosol (after reconstitution) may produce respiratory irritation, shortness of breath, and coughing. In clinical use, bivalirudin may produce hematological effects (e.g. increased bleeding), cardiovascular effects (potentially fatal thrombosis), and sensitivity-like reactions. In clinical use, non-hemorrhagic adverse effects include back pain, pain (unspecified), nausea, headache, hypotension, injection site pain, insomnia, hypertension, vomiting, pelvic pain, anxiety, bradycardia, dyspepsia, abdominal pain, fever, nervousness, and urinary retention. pain, anxiety, bradycardia, dyspepsia, abdominal pain, fever, nervousness, and urinary retention.
c)	Delayed and immediate effects and also chronic effects from short and long term exposure	None anticipated from normal handling of this product. However, inadvertent skin contact with this product formulation may cause irritation and redness. Sodium hydroxide has produced severe skin irritation in a study in rabbits. Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

d) Acute Toxicity:

Component	Type	Route	Species	Dosage
Bivalirudin	LD50	Subcutaneous	Rat, Rabbit	>150mg/kg
Sodium acetate trihydrate	LD50	NA	NA	NA
Polyethylene Glycol 400	LD50	Oral	Rabbit	26800 mg/kg
	LD50	Dermal	Rabbit	>20000 mg/kg
Mannitol	LD50	Oral	Rat	13500 mg/kg
Sodium Hydroxide	LD50	Oral	Rabbit	500mg/kg



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Reproductive Effects: None anticipated from normal handling of this product. Fertility and general reproductive performance in rats were unaffected by subcutaneous doses of bivalirudin up to 150 mg/kg/day. Teratogenicity studies have been performed in rats at subcutaneous doses up to 150 mg/kg/day and rabbits at subcutaneous doses up to 150 mg/kg/day. No evidence of impaired fertility or harm to the fetus attributable to bivalirudin was noted in these studies.

e) **Hazardous Chemical Listings**

NTP: Not Listed IARC: Not Listed OSHA: carcinogen.

SECTION 12 – ECOLOGICAL INFORMATION

a)	Ecotoxicity	Not determined for product. LC50(48hr, flow through) = 189 mg/l in freshwater fish for sodium hydroxide LC50(24hr, static) = 125-160 mg/l in freshwater fish for sodium hydroxide LC50(48hr, static) = 125 mg/l in freshwater fish for sodium hydroxide LC50(96hr static) = 45.4 – 125 mg/l in freshwater fish for sodium hydroxide EC(1ethality) = 100 - 156 mg/l in Daphnia for sodium hydroxide
b)	Persistence and degradability	Not determined for product. Bivalirudin is susceptible to bacterial degradation.
c)	Bioaccumulative potential	Not established
d)	Mobility in soil	Not established
e)	Other Adverse Effects	Not established

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

SECTION 14 – TRANSPORTATION INFORMATION

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

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



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SECTION 15 – REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible 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 – Exempt. However, sodium hydroxide is listed on the TSCA inventory

CERCLA - RQ = 1000 lbs (454 kg) for sodium hydroxide

SARA 302 - Not on this list

SARA 313 - Not on this list

Prop 65 (Calif.) – Not on this list

RCRA – Not on this list

SECTION 16 – OTHER INFORMATION

As of the date of issuance, 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.



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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
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
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)