



Product name: Bivalirudin for injection

Issue date: 05-08-21

SDS

Safety Data Sheet

SDS No. :21868980511301



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1. Product and Company Identification

Product name : Bivalirudin for injection

Product use : Used as an anticoagulant

Manufacturer/Supplier : Hainan Poly Pharm. CO., LTD

Address : No.2 Xingyang Road, Guilinyang Economic Development Area, Haikou, Hainan 571127, P.R.China

Telephone : +86 898-36389016

E-mail : hnpoly@hnpoly.com

Emergency telephone number of the company : +86 898-36389016

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

GHS classification of the product : Not classified as hazardous according to OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Label elements

Pictogram : Not applicable.

Signal word : Not applicable.

Hazards not otherwise classified : Not applicable.

3. Composition / Information on Ingredients

Chemical nature: mixture

Components

Chemical Name	CAS-No.	Concentration
Bivalirudin	128270-60-0	61%
Mannitol	87-78-5	30%
Sodium hydroxide	1310-73-2	9%

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4. First-Aid Measures

Description of first aid measures

- Inhalation** : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Skin contact** : Wash off immediately with soap and plenty of water. If irritation occurs or persists, get medical attention.
- Eye contact** : Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
- Ingestion** : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Most important symptoms and effects, both acute and delayed** : No information available.

Indication of any immediate medical attention and special treatment needed

Note to physician : None

5: Fire-Fighting Measures

Suitable extinguishing media : Extinguish fires with CO₂, extinguishing powder, foam, or water.

Unsuitable extinguishing media : No information available.

Special hazards arising from the substance or mixture

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 hydro carbon compounds may be released in small quantities depending upon specific conditions of combustion.

Advice for firefighters : Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

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Special protective equipment for firefighters : As in any fire, wear Self-Contained Breathing Apparatus(SCBA), MSHA/NIOSH(approved or equivalent) and full protective gear.

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 materials for containment and 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.

7: Handling and storage

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.

Conditions for safe storage, including any incompatibilities : Store as directed by product packaging.

8: Exposure Controls/Personal Protection

Control parameters

Chemical name	Occupational Exposure Limits		Regulation
Sodium hydroxide	PEL TWA	2 mg/m ³	OSHA
Sodium hydroxide	TLV TWA	2 mg/m ³	ACGIH

Personal protective equipment

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.

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- Hand protection** : Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations.
- Eye protection** : Wear safety glasses or goggles if eye contact is possible.
- Skin and body protection** : Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

9: Physical and chemical properties

- Form** : loose lumps or powder
- Colour** : white
- Odour** : no data available
- pH** : 5.0-6.0
- Melting point** : no data available
- Boiling point** : no data available
- Flash point** : no data available
- Thermal decomposition temperature** : no data available
- Density** : no data available
- Water solubility** : soluble
- Viscosity, dynamic** : not applicable

10: Stability and Reactivity

- Reactivity** : No data available.
- Chemical stability** : Stable under normal conditions of use.
- Possibility of hazardous reactions** : No data available.
- Conditions to avoid** : Avoid dust formation.

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Incompatible materials : Keep away from strong oxidizers.

Hazardous decomposition products : Carbon monoxide, carbon dioxide, nitrogen oxides.

11: Toxicological information

Acute toxicity

Acute oral toxicity
No information available

Acute inhalation toxicity
No information available

Acute dermal toxicity
No information available

Skin corrosion/irritation

Effect of irritation assessment
non-irritant

Serious eye damage/irritation

Effect of irritation assessment
non-irritant

Respiratory or skin sensitisation

Sensitisation assessment
non-sensitizing

Germ cell mutagenicity

Mutagenic effects assessment:
According to the known information,not classified.

Carcinogenicity

Carcinogenicity assessment:
According to the known information,not classified.

Reproductive toxicity

Reproductive toxicity assessment:
According to the known information,not classified.

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STOT-single exposure

Specific target organ toxicity (single exposure) toxicity assessment:
According to the known information,not classified.

STOT-repeated exposure

Specific target organ toxicity (repeated exposure) toxicity assessment:
According to the known information,not classified.

Aspiration hazard

Aspiration hazard assessment
According to the known information,not classified.

12: Ecological information

Ecotoxicity

No information available

Persistence and degradability

No information available

Bioaccumulative potential

No information available

Mobility in soil

No information available

Other adverse effects

No information available

13: Disposal considerations

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

Contaminated packaging : Dispose of container and unused contents in accordance with federal, state and local regulations.

14: Transport Information

Land transport

DOT

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UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Packing group : Not applicable

Sea transport

IMDG

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Packing group : Not applicable

Air transport

IATA/ICAO

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Packing group : Not applicable

15: Regulatory information

Federal Regulations

Registration status:

Chemical TSCA, US released / listed

EPCRA 311/312 (Hazard categories): not hazardous

CA Prop. 65:

There are no listed chemicals in this product.

NFPA Hazard codes:

Health : 0 Fire: 0 Reactivity: 0 Special:

CERCLA RQ CAS Number Chemical name

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1000LBS

1310-73-2

Sodium hydroxide

HMIS III rating

Health: 0

Flammability: 0

Physical hazard: 0

16: Other information

SDS Prepared by:

Cairui Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 05-08-21

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