



Product name: Eptifibatide Injection (20mg/10ml)

Issue date: 03/27/19

SDS

Safety Data Sheet

SDS No. : 19868980327301



Creator: BDT Chemical Technology (Shanghai) CO.,LTD

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SAFETY DATA SHEET

Version 1.0

Revision Date: 03/27/19

1. Product and Company Identification

Product name : Eptifibatide Injection (20mg/10ml)

Product use : It is used in the management of unstable angina and in patients undergoing coronary angioplasty and stenting procedures. It has a role as a platelet aggregation inhibitor and 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 65712762

E-mail : hnpoly@hnpoly.com

Emergency telephone number of the company : +86 898 65712762

2. Hazards Identification

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

GHS classification of the product : Eye damage/irritation category 2
Specific target organ toxicity (single exposure) category 1

Label elements

Pictogram : 

Signal word : Danger

Hazard statement : Causes serious eye irritation
Causes damage to organs (blood)

Precautionary statements

Prevention : Wash exposed skin thoroughly after handling.
Wear protective gloves / protective clothing / eye protection / face protection.
Do not breathe dust/fume/gas/mist/ vapours/spray.

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- Response** : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF exposed: Call a POISON CENTER or doctor/physician.
Specific treatment (see section 4 on this SDS).
- Storage** : Store locked up.
- Disposal** : Dispose of contents/container in accordance with local/regional/national/international regulations.
- Hazards not otherwise classified** : No specific dangers known, if the regulations/notes for storage and handling are considered.

3. Composition / Information on Ingredients

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

Components

Chemical Name	CAS-No.	Concentration
Eptifibatide	188627-80-7	20-25%
Citric acid	77-92-9	15-20%
Trisodium citrate	6132-04-3	60-65%

4. First-Aid Measures

Description of first aid measures

- Inhalation** : If difficulties occur after vapour has been inhaled, remove to fresh air and seek medical attention.
- Skin contact** : After contact with skin, wash immediately with plenty of water. If irritation persists, consult a physician.
- Eye contact** : If you use contact lenses, remove the lenses first. Wash affected eyes for at least 15 minutes under running water with eyelids held open. If symptoms occur, consult a physician, preferably an ophthalmologist.
- Ingestion** : Rinse mouth immediately and then drink plenty of water, seek medical attention.

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Most important symptoms and effects, both acute and delayed : Aside from the information found under Description of first aid measures (above) and Indication of immediate medical attention and special treatment needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

Indication of any immediate medical attention and special treatment needed

Note to physician : Treatment of exposure should be directed at the the clinical condition of the patient.

5: Fire-Fighting Measures

Suitable extinguishing media : Water fog or fine spray.Dry chemical fire extinguishers.Carbon dioxide fire extinguishers.

Unsuitable extinguishing media : No data available.

Special hazards arising from the substance or mixture

Hazardous combustion products : During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating.Combustion products may include and are not limited to: Carbon monoxide.Carbon dioxide. Nitrogen oxide.

Advice for firefighters

Special protective equipment for firefighters : Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves).If protective equipment is not available or not used, fight fire from a protected location or safe distance.

6: Accidental release measures

Personal precautions, protective equipment and emergency procedures : Avoid eye contact. Use personal protective equipment.

Environmental precautions : Contain contaminated water/firefighting water. Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

Methods and materials for containment and cleaning up : Contain spilled material if possible.Collect in suitable and properly labeled containers.

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7: Handling and storage

Advice on safe handling : Avoid contact with the skin, eyes and clothing .Ensure adequate ventilation.

Conditions for safe storage, including any incompatibilities : Keep tightly closed in a well-ventilated place. Should be refrigerated at between 2-8 deg C and protected from light until administration.

8: Exposure Controls/Personal Protection

Control parameters : No data available.

Personal protective equipment

Respiratory protection : None required under normal conditions. Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines.

Hand protection : Handle with gloves.

Eye protection : In case of risk of spray, Use safety glasses (with side shields).

Skin and body protection : Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

9: Physical and chemical properties

Form : liquid

Colour : clear

Odour : none

pH : 5.2-5.5

Melting point : no data available

Boiling point : no data available

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Flash point : no data available

Thermal decomposition temperature : no data available

Relative density : no data available

Water solubility : no data available

Viscosity, dynamic : no data available

10: Stability and Reactivity

Reactivity : No hazardous reactions if stored and handled as prescribed/indicated.

Chemical stability : Stable under recommended storage conditions.

Possibility of hazardous reactions : This material is considered stable.

Conditions to avoid : Avoid temperatures below 2 or above 8 C, avoid sun light.

Incompatible materials : Avoid contact with: Strong alkali, strong acid, strong oxidizers.

Hazardous decomposition products : Carbon monoxide. Carbon dioxide. Nitrogen oxide. Sulfur dioxide.

11: Toxicological information

Information on toxicological effects

Acute toxicity

Acute Toxicity: oral

Trisodium citrate
LD50/mouse: 5 400 mg/kg bw

Citric acid
LD50/mouse: 5 400 mg/kg bw

Acute Toxicity: inhalation

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no data available

Acute Toxicity: dermal

Trisodium citrate

LD50/rat:> 2 000 mg/kg bw

Citric acid

LD50/rat:> 2 000 mg/kg bw

Skin irritation/corrosion

Trisodium citrate

rabbit

not irritating

Citric acid

rabbit

not irritating

Serious eye damage/irritation

Causes serious eye irritation

Respiratory or skin sensitisation

Trisodium citrate

guinea pig

not sensitising

Germ cell mutagenicity

Evidence analysis showed that the substance did not induce gene mutations.

Carcinogenicity

Evidence analysis showed that the substance was not a carcinogen.

Reproductive toxicity

Animal tests showed no developmental toxicity.

STOT-single exposure

No information available

STOT-repeated exposure

No information available

Aspiration hazard

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Version 1.0

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No information available

12: Ecological information

Aquatic Toxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

13: Disposal considerations

Product : Observe national and local legal requirements.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14: Transport Information

Land transport

DOT

UN number : not applicable

UN proper shipping name : not applicable

Transport hazard class(es) : not applicable

Packing group : not applicable

Sea transport

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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): Acute

CA Prop. 65:

There are no listed chemicals in this product.

NFPA Hazard codes:

Health : 3 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 3 Flammability: 1 Physical hazard: 0

16: Other information

SDS Prepared by:

BDT Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 27/03/19

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The information herein is provided in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws. The information presented here pertains only to the product as shipped. Since conditions for use of the product are not under the control of the manufacturer, it is the buyer's/user's duty to determine the conditions necessary for the safe use of this product. Due to the proliferation of sources for information such as manufacturer-specific SDSs, we are not and cannot be responsible for SDSs obtained from any source other than ourselves. If you have obtained an SDS from another source or if you are not sure that the SDS you have is current, please contact us for the most current version.



Product name: Eptifibatide Injection (75mg/100ml)

Issue date: 03/27/19

SDS

Safety Data Sheet

SDS No. : 19868980327302



Creator: BDT Chemical Technology (Shanghai) CO.,LTD

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Mobility in soil

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Other adverse effects

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DOT

UN number : not applicable

UN proper shipping name : not applicable

name :

Transport hazard class(es) : not applicable

class(es) :

Packing group : not applicable

Sea transport

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Version 1.0

Revision Date: 03/27/19

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): Acute

CA Prop. 65:

There are no listed chemicals in this product.

NFPA Hazard codes:

Health : 3 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 3 Flammability: 1 Physical hazard: 0

16: Other information

SDS Prepared by:

BDT Chemical Technology (Shanghai) CO.,LTD

SDS Prepared on: 27/03/19

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