

# SAFETY DATA SHEET



## Eptifibatide Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 42732-00022 Date of last issue: 04.04.2023 Date of first issue: 05.01.2015

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### Section 1: Identification

Product name : Eptifibatide Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Specific target organ toxicity - : Category 2 (Blood)  
single exposure (Oral)

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H371 May cause damage to organs (Blood) if swallowed.

Precautionary statements : **Prevention:**

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

#### Response:

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

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### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

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## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Eptifibatide	188627-80-7	>= 1 - < 10

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## Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : May cause damage to organs if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

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## Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical

Unsuitable extinguishing : None known.

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Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**Section 6: Accidental release measures**

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**Section 7: Handling and storage**

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling.

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Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Eptifibatide	188627-80-7	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

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Material	: Chemical-resistant gloves
Remarks Eye protection	: Consider double gloving. : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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### Section 9: Physical and chemical properties

Appearance	: liquid
Colour	: colourless
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Density	: No data available

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Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle size	: No data available

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### Section 10: Stability and reactivity

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

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### Section 11: Toxicological information

Exposure routes	: Inhalation Skin contact Ingestion Eye contact
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#### Acute toxicity

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

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Not classified based on available information.

**Components:****Eptifibatide:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : Not a skin sensitizer.

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Eptifibatide:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: Mouse Lymphoma  
Result: negative  
  
Test Type: sister chromatid exchange assay  
Test system: Human lymphocytes  
Result: negative  
  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Eptifibatide:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Fertility: NOAEL: < 72 mg/kg body weight  
Result: No effects on fertility  
  
Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intravenous injection

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Developmental Toxicity: NOAEL: 72 mg/kg body weight  
Result: No effects on foetal development

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 36 mg/kg body weight  
Result: No effects on foetal development

### STOT - single exposure

May cause damage to organs (Blood) if swallowed.

#### Components:

##### **Eptifibatide:**

Exposure routes : Ingestion  
Target Organs : Blood  
Assessment : Causes damage to organs.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **Eptifibatide:**

Species : Rat  
NOAEL : > 72 mg/kg  
Application Route : Intravenous  
Exposure time : 28 d  
Remarks : No significant adverse effects were reported

Species : Monkey  
NOAEL : 7.2 mg/kg  
Exposure time : 28 d  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **Eptifibatide:**

Ingestion : Symptoms: bleeding

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### Section 12: Ecological information

#### Ecotoxicity

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

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### Section 13: Disposal considerations

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Contaminated packaging : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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### Section 14: Transport information

#### International Regulations

##### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable

##### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

UN number : Not applicable

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Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### NZS 5433

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

### Special precautions for user

Not applicable

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## Section 15: Regulatory information

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

#### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

### The components of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## Section 16: Other information

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#### Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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compile the Safety Data Sheet eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyy

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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