


# SAFETY DATA SHEET

## Eptifibatide Injection

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Eptifibatide Injection
<b>Synonyms:</b>	Eptifibatide
<b>National Drug Code (NDC):</b>	17478-902-10 17478-902-90 17478-903-90
<b>Recommended Use:</b>	Pharmaceutical. Eptifibatide Injection is indicated to decrease the rate of a combined endpoint of death, new myocardial infraction, or need for urgent intervention in patients undergoing percutaneous coronary intervention.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.	
<b>Health Hazards:</b>	Skin irritation	Category 2
	Eye irritation	Category 2A
<b>Symbol(s):</b>		
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H315 Causes skin irritation.	
	H319 Causes serious eye irritation.	
<b>Precautionary Statement(s):</b>	P233 Keep container tightly closed.	
	P264 Wash potentially exposed skin after handling.	
	P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
	+ P351	
	+ P338	

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- P337 If eye irritation persists: Get medical advice/attention.  
+  
P313
- P332 If skin irritation occurs: Get medical advice/attention.  
+  
P313
- P308 IF exposed or concerned: Get medical advice/attention.  
+  
P313
- P403 Store in a well-ventilated place.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

**Hazards Not Otherwise Classified:** None.  
**Supplementary Information:** None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Eptifibatide	N <sup>6</sup> -(aminoiminomethyl)-N <sup>2</sup> -(3-mercapto-1-oxopropyl)-Llysylglycyl-L-α-aspartyl-L-tryptophyl-L-prolyl-L-cysteinamide, cyclic (1→6)-disulfide	188627-80-7	C <sub>35</sub> H <sub>49</sub> N <sub>11</sub> O <sub>9</sub> S <sub>2</sub>	831.96	0.075% or 0.2%

Each 10 mL vial contains 2 mg/mL of Eptifibatide and each 100 mL vial contains either 0.75 mg/mL of Eptifibatide or 2 mg/mL of Eptifibatide. Each vial of either size also contains 5.25 mg/mL Citric Acid and Sodium Hydroxide to adjust the pH to 5.35.

### 4. FIRST AID MEASURES

**Ingestion:**

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

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<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Impaired blood coagulation and bleeding have been reported in therapeutic use.
<b>Medical Conditions Aggravated by Exposure:</b>	Bleeding, thrombocytopenia.
<b>Notes to Physician:</b>	Treat supportively and symptomatically. Eptifibatide Injection can cause serious bleeding. If bleeding cannot be controlled, discontinue Eptifibatide Injection immediately.

### 5. FIREFIGHTING MEASURES

**Suitable Extinguishing Media:** Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.

**Unsuitable Extinguishing Media:** Not determined.

#### Specific Hazards Arising from the Chemical

**Hazardous Combustion Products:** During fire, gases hazardous to health may be formed.

**Other Specific Hazards:** Closed containers may explode from the heat of fire.

**Special Protective Equipment and Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

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### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Do not touch or walk through spilled material. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store refrigerated at 2° to 8°C (36° to 46°F). Vials may be transferred to room temperature 25°C (77°F) [See USP Controlled Room Temperature] for up to 2 months. Upon transfer, vial carton must be marked by the dispensing pharmacist with a "DISCARD BY" date (2 months from the transfer date or the labelled expiration date, whichever comes first).

**Specific End Use:** Pharmaceutical drug product.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Eptifibatide	8 Hour TWA	70 mcg/m <sup>3</sup>

*TWA: Time Weighted Average*

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

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<b>Eyes Protection:</b>	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand Protection:</b>	Chemically compatible gloves are recommended. For handling solutions ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
<b>General Hygiene Considerations:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Clear, colorless solution.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	5.35.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.

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**Possibility of Hazardous Reactions:** No dangerous reaction known under conditions of normal use.

**Conditions to Avoid (e.g., static discharge, shock, or vibration):** Contact with incompatible materials.

**Incompatible Materials:** Strong oxidizing agents.

**Hazardous Decomposition Products:** None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

**Inhalation:** None under normal use conditions.

**Ingestion:** May be harmful if swallowed.

**Skin Contact:** Causes skin irritation.

**Eye Contact:** Causes eye irritation.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

#### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
No data available	No data available	No data available	No data available	No data available

#### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

#### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

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### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

**Aspiration Hazard:** No data available.  
**Toxicokinetics/Metabolism:** No data available.  
**Target Organ Effects:** No data available.  
**Systemic Effects:** No data available.

**Reproductive Effects:** Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women with Eptifibatide Injection.

**Carcinogenicity:** No long-term studies in animals have been performed to evaluate the carcinogenic potential of Eptifibatide.

**National Toxicology Program (NTP):** Not considered to be a carcinogen.

**International Agency for Research on Cancer (IARC):** Not considered to be a carcinogen.

**Occupational Safety and Health Administration (OSHA):** Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

**Terrestrial Toxicity:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

## 13. DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

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### 14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Eptifibatide	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

#### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Eptifibatide	Listed	Listed	Not Listed



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## Eptifibatide Injection

**California Proposition 65:**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### 16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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