Safety Data Sheet

## **SECTION 1: Identification**

1.1. Identification

Product name : Eptifibatide Injection

Other means of identification : 0.75 mg/mL, 100 mL SDV NDC 55150-218-99 2 mg/mL, 10 mL SDV NDC 55150-219-10

2 mg/mL, 100 mL SDV NDC 55150-220-99

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics 6 Wheelling Road Dayton, NJ 08810 T 609-642-1136

## 1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

## SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

## **Classification (GHS-US)**

Skin Irrit. 2 H315 Eye Irrit. 2A H319

Full text of H-phrases: see section 16

#### 2.2. Label elements

#### **GHS-US** labeling

Hazard pictograms (GHS-US)



GHS07

Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : H315 - Causes skin irritation

H319 - Causes serious eye irritation

Precautionary statements (GHS-US) : P264 - Wash thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302+P352 - If on skin: Wash with plenty of water

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P332+P313 - If skin irritation occurs: Get medical advice/attention P337+P313 - If eye irritation persists: Get medical advice/attention P362+P364 - Take off contaminated clothing and wash it before reuse

## 2.3. Other hazards

No additional information available

## 2.4. Unknown acute toxicity (GHS US)

Not applicable

## **SECTION 3: Composition/information on ingredients**

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	100	Not classified

09/09/2015 EN (English US) Page 1

## Safety Data Sheet

Name	Product identifier	%	Classification (GHS-US)
Sodium hydroxide	(CAS No) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Citric acid monohydrate	(CAS No) 5949-29-1	< 1	Eye Irrit. 2A, H319
Eptifibatide	(CAS No) 188627-80-7	< 1	Not classified

Full text of H-phrases: see section 16

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.

First-aid measures after skin contact : Drench affected area with water.

First-aid measures after eye contact : Rinse immediately with tap water for 10 minutes - open eyelids forcibly.

First-aid measures after ingestion : Seek immediate medical attention.

## 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : None under normal use conditions.

Symptoms/injuries after skin contact : Causes skin irritation.

Symptoms/injuries after eye contact : Causes serious eye irritation.

Symptoms/injuries after ingestion : May be harmful if swallowed.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

## 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

#### 5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear full protective gear.

## **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

#### 6.1.1. For non-emergency personnel

No additional information available

## 6.1.2. For emergency responders

No additional information available

## 6.2. Environmental precautions

Prevent entry to sewers and public waters.

## 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Confine spill and soak up with absorbent. Place in an approved container and dispose in

accordance with local, state and federal regulations.

#### 8.4. Reference to other sections

No additional information available

## **SECTION 7: Handling and storage**

## 7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with eyes, skin or clothing. Wash after handling.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Vials should be stored refrigerated at 2° to 8°C (36° to 46°F). Vials may be transferred to room

temperature storage 20° to 25°C (68° to 77°F) for a period not to exceed 2 months.

09/09/2015 EN (English US) 2/5

Safety Data Sheet

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

Sodium hydroxide (1310-73-2	m hydroxide (1310-73-2)	
ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³
OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³

## 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use neoprene or rubber gloves.

Eye protection : Safety glasses.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : None necessary during normal operations.

## **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : Colorless
Odor : Odorless

Odor threshold : No data available

pH : 5.35

Melting point No data available Freezing point No data available Boiling point : No data available Flash point No data available Relative evaporation rate (butyl acetate=1) : No data available : No data available Flammability (solid, gas) **Explosion limits** No data available Explosive properties : No data available Oxidizing properties : No data available Vapor pressure : No data available Relative density : No data available Relative vapor density at 20 °C : No data available Solubility : Completely soluble. Log Pow No data available : No data available Auto-ignition temperature : No data available Decomposition temperature No data available Viscosity Viscosity, kinematic : No data available Viscosity, dynamic : No data available

#### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

## 10.1. Reactivity

No additional information available

## 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

## 10.3. Possibility of hazardous reactions

Will not occur.

09/09/2015 EN (English US) 3/5

## Safety Data Sheet

#### 10.4. Conditions to avoid

None

## 10.5. Incompatible materials

None known.

## 10.6. Hazardous decomposition products

None known.

## **SECTION 11: Toxicological information**

#### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg

Sodium hydroxide (1310-73-2)	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350.000 mg/kg

Skin corrosion/irritation : Causes skin irritation.

pH: 5.35

Serious eye damage/irritation : Causes serious eye irritation.

pH: 5.35

Respiratory or skin sensitization : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified

Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated

exposure)

: Not classified

Aspiration hazard : Not classified

## **SECTION 12: Ecological information**

## 12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

## 12.2. Persistence and degradability

No additional information available

## 12.3. Bioaccumulative potential

No additional information available

## 12.4. Mobility in soil

No additional information available

## 12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

09/09/2015 EN (English US) 4/5

## Safety Data Sheet

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

## **Department of Transportation (DOT)**

In accordance with DOT Not regulated for transport

## **SECTION 15: Regulatory information**

## 15.1. US Federal regulations

## Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

## Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

## 15.2. US State regulations

## Sodium hydroxide (1310-73-2)

- U.S. Massachusetts Right To Know List
- U.S. Minnesota Hazardous Substance List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

## **SECTION 16: Other information**

#### Full text of H-phrases:

Xt Of Π-prifases.	
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

09/09/2015 EN (English US) 5/5