
	Sagent Pharmaceuticals, Inc.		
	Document Type Safety Data Sheet (SDS)	Document Title Eptifibatide Injection	
	Document No. MSDS-0094	Version 1.0	Effective Date 7/18/2018

Section 1 - Identification

- (a) **Product Identifier:** Eptifibatide Injection
- (b) **Product Code:** 25021-408, 25021-409, 25021-412, 25021-413
- Common/Trade Name:** Eptifibatide Injection
- Chemical Name:** N6 -(Aminoiminomethyl)-N2-(3-mercapto-1-oxopropyl-L-lysylglycyl-L-(alpha)-aspartyl-Ltryptophyl-L-prolyl-L-cysteinamide, cyclic (1->6)-disulfide
- Chemical Family:** Cyclic heptapeptide
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial, IV Bag
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** **NFPA Rating**
Health Hazard : 0
Fire Hazard : 0
Reactivity Hazard : 0
- (b) **Signal Word,** Warning
Hazard statement(s), Prolonged or repeated exposure may cause damage to organs.
Symbol(s), and/or (In the case of accident or if you feel unwell, seek medical
Precautionary advice immediately (show the label where possible). Ensure
statement(s): that medical personnel are aware of the material(s) involved,
and take precautions to protect themselves
- (c) **Description of Hazards:** May cause damage to organs through prolonged or repeated exposure.
- (d) **Unknown Acute Toxicity:** N/A


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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure		(c) CAS No.	(d) Impurities / Stabilizing Additives
N6(Aminoiminomethyl)-N2-(3-mercapto-1-oxopropyl-L-lysylglycyl-L-(alpha)-aspartyl-L-tryptophyl-L-prolyl-L-cysteinamide, cyclic (1->6)-disulfide	Eptifibatide	0.75 mg/mL	2 mg/mL	188627-80-7	n/a
2-Hydroxy-1,2,3-propanetricarboxylic acid monohydrate	Citric acid Monohydrate	4.80 - 5.250 mg/mL		5949-29-1	n/a
Sodium Hydroxide	Sodium Hydroxide	q.s. for pH adjustment		1310-73-2	n/a
Water	Water for Injection	q.s. to 1 mL		7732-18-5	n/a
Nitrogen	Nitrogen	As required		7727-37-9	n/a

Section 4 - First Aid Measures

- Eye Exposure:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- Skin Exposure:** Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
- Ingestion:** If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
- Injection:** In cases of accidental injection, wash and disinfect area, get medical attention.
- Inhalation:** Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Water, foam, dry chemical powder, carbon dioxide (CO₂).
- (b) **Hazardous Combustion Products:** Not available
- (c) **Special Protective Equipment / Precautions:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Section 6 - Accidental Release Measures

- Spill:** Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
- Release to Air:** N/A
- Release to Water:** Avoid discharge into drains, water courses or onto the ground.

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Section 7 - Handling and Storage

General Handling: Gloves, masks and goggles are recommended during handling of samples for analysis.

Storage Conditions: Store at a temperature 2°C to 8°C (36°F-46°F). Protect from light. Do not freeze.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
<i>Eptifibatide</i>	<i>GSK</i>	<i>8 HR TWA</i>	<i>70 mcg/m³</i>

(b) Engineering Controls

Ventilation: General ventilation normally adequate.


(c) Individual Protection Measures

Respiratory Protection:	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Eye Protection:	Safety glasses with side shields are recommended if contact is likely.
Skin Protection:	For Prolonged or repeated skin contact use suitable protective gloves.
Other Protective Equipment:	Wear appropriate protective clothing, when necessary (i.e. against splashing or contamination).
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product. Wash work clothes and protective equipment to remove contaminants.

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Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear, colorless solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	5.20-5.50
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

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Section 10 - Stability and Reactivity

(a)	Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use
(d)	Conditions to Avoid	Contact with incompatible materials.
(e)	Incompatible Materials	Strong Oxidizing agents
(f)	Hazardous Decomposition Products	Not known. Irritating and/or toxic fumes and gases maybe emitted upon the products decomposition.

Section 11 - Toxicological Information


(a)	Likely Routes of Exposure	Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Not known. The following adverse effects under therapeutic use: impaired blood coagulation; bleeding
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Health injuries not known or expected under normal use.

(d) Acute Toxicity

Health injuries are not known or expected under normal use.

(e) Hazardous Chemical Listings

NTP: Not available IARC: Not available OSHA: Not listed

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Section 12 - Ecological Information

(a)	Ecotoxicity	Not expected to harm aquatic organisms.
(b)	Persistence and degradability	N/A
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	Not available
(e)	Other Adverse Effects	N/A


Section 13 - Disposal Considerations

Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Consult the appropriate state, regional, or local regulations for additional requirements.

Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

IATA: Not regulated
 DOT: Not regulated
 IMDG: Not regulated

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.


U.S. Regulations:

TSCA: Not regulated

CERCLA: Not listed

SARA 302: Not listed

SARA 313: Not regulated

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Section 16 - Other Information


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient

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LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System