

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Argatroban Injection

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical product; Direct thrombin inhibitor / Anticoagulant

1.3. Name, Address, and Telephone of the Responsible Party

Company

Endo USA Inc
870 Parkdale Rd
Rochester, MI 48307 USA
1-800-828-9393 (Phone)
1-201-829-9222 (Fax)

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Flam. Liq. 3 H226

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS02

Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

H226 - Flammable liquid and vapor.

Precautionary Statements (GHS-US) :

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed.
P240 - Ground/Bond container and receiving equipment.
P241 - Use explosion-proof electrical, ventilating, and lighting equipment.
P242 - Use only non-sparking tools.
P243 - Take precautionary measures against static discharge.
P280 - Wear protective gloves, protective clothing, and eye protection.
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P370+P378 - In case of fire: Use appropriate media (see section 5) to extinguish.
P403+P235 - Store in a well-ventilated place. Keep cool.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
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Water	AQUA / Water for injection	(CAS-No.) 7732-18-5	84.64	Not classified
Ethyl alcohol	Methylcarbinol / Ethanol / Alcohol anhydrous / Alcohol / Grain alcohol	(CAS-No.) 64-17-5	7.69	Flam. Liq. 2, H225 Eye Irrit. 2A, H319
D-Glucitol	Sorbitol / D-Sorbitol / Sorbitol, D-	(CAS-No.) 50-70-4	5.76	Comb. Dust
Argatroban anhydrous	(2R,4R)-1-[(2S)-5-Guanidino-2-(1,2,3,4-tetrahydro-3-methyl-8-quinolyl sulfonyl amino)valeryl]-4-methyl-2-piperidine carboxylic acid	(CAS-No.) 74863-84-6	1.92	Aquatic Acute 3, H402 Aquatic Chronic 2, H412

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Immediately remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, alcohol foam, polymer foam, carbon dioxide, dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Flammable liquid and vapor. Will not sustain combustion.

Explosion Hazard: May form flammable or explosive vapor-air mixture. Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Reactivity: Reacts violently with strong oxidizers. Increased risk of fire or explosion.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrous fumes. Nitrous oxide. Sulfur oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing (vapor, mist, spray). Do not get in eyes, on skin, or on clothing. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Use special care to avoid static electric charges. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel. Stop leak if safe to do so.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

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Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Eliminate ignition sources first, then ventilate the area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods for Cleaning Up: Use only non-sparking tools. Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Do not take up in combustible material such as: saw dust or cellulosic material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents. Handle empty containers with care because residual vapors are flammable. Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, spray. Take precautionary measures against static discharge. Use only non-sparking tools. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Take action to prevent static discharges. Ground and bond container and receiving equipment. Use explosion-proof electrical, ventilating, and lighting equipment.

Storage Conditions: Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in a well-ventilated place. Keep container tightly closed. Keep out of reach of children.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C / 68 – 77 °F (See USP Controlled Room Temperature)

Storage Area: Do not freeze. Protect from light.

7.3. Specific End Use(s)

Pharmaceutical product; Direct thrombin inhibitor / Anticoagulant

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH OEL STEL	1000 ppm
USA ACGIH	ACGIH chemical category	Confirmed Animal Carcinogen with Unknown Relevance to Humans
USA NIOSH	NIOSH REL TWA	1900 mg/m ³
USA NIOSH	NIOSH REL TWA	1000 ppm
USA IDLH	IDLH	3300 ppm (10% LEL)
USA OSHA	OSHA PEL TWA	1900 mg/m ³
USA OSHA	OSHA PEL TWA	1000 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when flammable gases or vapors may be released. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment.

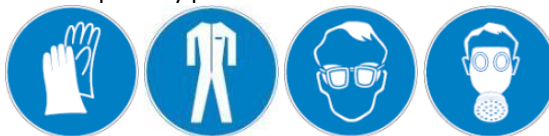
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Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics. Wear fire/flame resistant/retardant clothing.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles or safety glasses with side shields.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless to pale yellow solution
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: > 35 °C / > 95 °F
Flash Point	: > 23 °C / > 73 °F
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: Water: soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reacts violently with strong oxidizers. Increased risk of fire or explosion.

10.2. Chemical Stability

Flammable liquid and vapor. May form flammable or explosive vapor-air mixture.

10.3. Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, heat, hot surfaces, sparks, open flames, incompatible materials, and other ignition sources.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified

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Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

Ethyl alcohol (64-17-5)	
LD50 Oral Rat	10470 mg/kg
LD50 Dermal Rat	20 ml/kg
LC50 Inhalation Rat	124.7 mg/l/4h
D-Glucitol (50-70-4)	
LD50 Oral Rat	15.9 g/kg
Argatroban anhydrous (74863-84-6)	
LD50 Oral Rat	> 15000 mg/kg
LD50 Oral Mouse	6200 mg/kg
LD50 Oral Dog	> 1000 mg/kg
LD50 IV Rat	138 mg/kg
LD50 IV Mouse	211 mg/kg
LD50 IV Dog	> 66 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

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

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Ethyl alcohol (64-17-5)	
LC50 Fish 1	11200 mg/l
EC50 Crustacea	9268 – 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
ErC50 Algae	1000 mg/l
NOEC Chronic Crustacea	9.6 mg/l

12.2. Persistence and Degradability

Argatroban Injection	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Argatroban Injection	
Bioaccumulative Potential	Not established.

Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Handle empty containers with care because residual vapors are flammable.

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Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Argatroban Injection	
SARA Section 311/312 Hazard Classes	Physical hazard - Flammable (gases, aerosols, liquids, or solids)
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Ethyl alcohol (64-17-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
D-Glucitol (50-70-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

15.2. US State Regulations

Ethyl alcohol (64-17-5)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision	: 06/06/2022
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H319	Causes serious eye irritation
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

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.

SDS US (GHS HazCom)