



Argatroban Injection

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Argatroban Injection

Synonyms: Argatroban Injection (Solution in Single Dose Vials) [250 mg / 2.5 mL]; Argatroban Injection 250 mg/2.5 mL (100 mg/mL)

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317, USA
+1.724.514.1800

Contact e-mail:

SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:

24 hr. Emergency Contact ChemTel

International: +1-813-248-0585

US & Canada: 1-800-255-3924

Mexico: 800-099-0731

Other Contact Information

FDA Adverse Events Reporting Number:

For reporting adverse health events call:
+1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Classification

Serious eye damage/eye irritation, Category 2A

Flammable liquids Category 2

Label elements



Signal word:

Danger

Hazard statements:

H319 - Causes serious eye irritation

H225 - Highly flammable liquid and vapor

Precautionary Statements - Prevention: Wash face, hands and any exposed skin thoroughly after handling
 Wear protective gloves/protective clothing/eye protection/face protection
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
 Keep container tightly closed
 Ground/bond container and receiving equipment
 Use only non-sparking tools
 Take precautionary measures against static discharge
 Use explosion-proof electrical/ ventilating/ lighting/ equipment

Precautionary Statements - Response:

Eyes: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

Skin: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

Fire: In case of fire: Use CO₂, dry chemical, or foam for extinction

Precautionary Statements - Storage: Store in a well-ventilated place. Keep cool

Precautionary Statements - Disposal: Dispose of contents/container to an approved waste disposal plant

Other Hazards

No information available.

Unknown acute toxicity

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Chemical name	CAS No	Weight-%	Hazard statements
Ethanol	64-17-5	30-50	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation
Argatroban	141396-28-3	<20	Not classified

4. FIRST AID MEASURES

Description of first aid measures

General advice: Show this safety data sheet to the doctor in attendance.

Inhalation: Remove to fresh air.

Skin contact: Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider: Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

Symptoms: Burning sensation. Dyspnea (breathing difficulty). Fever. Diarrhea. May decrease blood pressure and cause other cardiac effects. Chest pain. Nausea. Vomiting. Headache.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray. Alcohol resistant foam.

Unsuitable extinguishing media: CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

Fire hazard: Flammable.

Explosive hazard: Not an explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Hazardous combustion products: Carbon oxides.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.

Firefighting instructions: Use water spray or fog; do not use straight streams.

Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Other Information: Refer to Section 9 for flammability properties.

Sensitivity to Static Discharge Yes.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions: Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods and material for containment and cleaning up

Methods for containment: Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up: Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Advice on safe handling: Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use with local exhaust ventilation. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers. Do not store near combustible materials. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep at temperatures between 20 and 25 °C (68 and 77 °F). Protect from light. Do not freeze. Keep out of reach of children. Store locked up.

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves. Impervious gloves.

Eye/face protection: Tight sealing safety goggles.

Skin and body protection: Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.

Respiratory protection: Use appropriate respiratory protection.

General hygiene considerations: Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Solution
Color:	Clear, colorless to pale yellow
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
VOC Content (%):	No data available

10. STABILITY AND REACTIVITY

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Heat, flames and sparks.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: May cause irritation of respiratory tract.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Eye contact: Causes serious eye irritation. May cause redness, itching, and pain.

Skin contact: May cause irritation. Prolonged contact may cause redness and irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Burning sensation. Dyspnea (breathing difficulty). Fever. Diarrhea. May decrease blood pressure and cause other cardiac effects. Chest pain. Nausea. Vomiting. Headache.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: May cause skin irritation.

Serious eye damage/eye irritation: Irritating to eyes.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

No information available.

Persistence and degradability

No information available.

Bioaccumulation

There is no data for this product.

Chemical name	Partition coefficient
Ethanol (CAS #: 64-17-5)	-0.32

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging: Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

California Hazardous Waste Status

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	Weight-%	California Hazardous Waste Status
Ethanol (CAS #: 64-17-5)	30-50	Toxic Ignitable

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG

UN Number

UN 1170

UN proper shipping name

Flammable liquid, n.o.s. Ethanol solution (Ethyl alcohol solution)

Transport hazard class(es)

Hazard Class: 3



Packing group

II

Environmental hazards

No

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Special Provisions

Shipper, please take note that in addition to limited and/or excepted quantity exemptions, the following Special Provisions may apply to this product.

US DOT: DOT - ORM-D; DOT - 24

TDG: TDG - 150

IMDG: IMDG - 223; IMDG - 144

IATA: IATA - A3; IATA - A58; IATA - A180

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations****Ozone-depleting substances (ODS):** Not applicable**Persistent Organic Pollutants:** Not applicable**The Rotterdam Convention:** Not applicable**US Federal Regulations****SARA 313:** Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations**US State Regulations:**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION**Revision Date:** 24-August-2020**Other Information:** This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.**Key or legend to abbreviations and acronyms used in the safety data sheet:****Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology
Phone number: +1 304-559-2595*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.**Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*