

SAFETY DATA SHEET
Argatroban Injection



SECTION 1: IDENTIFICATION

GHS Product Identifier	:	Argatroban Injection
Chemical Name	:	1-[5-[(aminoiminomethyl)amino]-1-oxo-2-[[1,2,3,4-tetrahydro-3-methyl-8-quinolanyl)sulfonyl]amino]pentyl]-4-methyl-2-piperidinecarboxylic acid, monohydrate
Other means of identification	:	Not Available
Product Code	:	Not Available
Product Type	:	Regulated prescription drug
Container Information	:	50 mL vial
Relevant identified uses of the substance or mixture and uses advised against		
Identified Uses	:	Heparin-Induced Thrombocytopenia Argatroban Injection is indicated for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT).
		Percutaneous Coronary Intervention Argatroban Injection is indicated as an anticoagulant in adult patients with or at risk for HIT undergoing percutaneous coronary intervention (PCI).
Supplier Details	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

SECTION 2: HAZARDS IDENTIFICATION

OSHA/HCS Status	:	While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
Classification of the substance or mixture	:	Not Classified.
GHS Label Elements	:	
Signal Word	:	No Signal Word.
Hazard Statements	:	No known significant effects or critical hazards.

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

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<u>Precautionary Statements</u>	
Prevention	: Not Applicable.
Response	: Not Applicable.
Storage	: Not Applicable.
Disposal	: Not Applicable.
Hazards not otherwise classified	: Not Known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance/Mixture	: Mixture	
Chemical Name	: 1-[5-[(aminoiminomethyl)amino]-1-oxo-2-[[1,2,3,4-tetrahydro-3-methyl-8-quinoliny] sulfonyl]amino]pentyl]-4-methyl-2-piperidinecarboxylic acid, monohydrate.	
Other means of identification	: Not Available.	
<u>CAS Number/Other Identifiers</u>		
Product Code	: Not Available.	
Active Pharmaceutical Ingredient	%	CAS Number
Argatroban	5-10	74863-84-6
There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.		
Occupational exposure limits, if available, are listed in Section 8.		
See Package Insert for further information.		

SECTION 4: FIRST AID MEASURES

<u>Description of necessary first aid measures</u>	
Eye Contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin Contact	: Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
Ingestion	: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
<u>Most important symptoms/effects, acute and delayed</u>	
<u>Potential Acute Health Effects</u>	
Eye Contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.

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Skin Contact	:	No known significant effects or critical hazards.
Ingestion	:	No known significant effects or critical hazards.
<u>Over-Exposure Signs/Symptoms</u>		
Eye Contact	:	No known significant effects or critical hazards.
Inhalation	:	No known significant effects or critical hazards.
Skin Contact	:	No known significant effects or critical hazards.
Ingestion	:	No known significant effects or critical hazards.
<u>Indication of immediate medical attention and special treatment needed, if necessary</u>		
Notes to Physician	:	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific Treatments	:	No specific treatment.
Protection of first-aiders	:	No action shall be taken involving any personal risk or without suitable training.
See toxicological information (Section 11)		

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing Media		
Suitable Extinguishing Media	:	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	:	None Known
Specific hazards arising from the chemical	:	No specific fire or explosion hazard.
Hazardous thermal decomposition products	:	No specific data.
Special protective actions for fire-fighters	:	No special measures are required.
Special protective equipment for fire-fighters	:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: ACCIDENTAL RELEASE MEASURES

<u>Personal precautions, protective equipment and emergency procedures</u>		
For Non-emergency Personnel	:	No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
For Emergency Responders	:	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non- emergency personnel".
Environmental Precautions	:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

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Caplin Steriles Limited

Methods and materials for containment and cleaning up

Small Spill	:	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
Large Spill	:	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Protective measures	:	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene	:	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
Conditions for safe storage, including any incompatibilities	:	Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control Parameters

<u>Occupational Exposure Limits</u>	:	None
Appropriate Engineering Controls	:	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
Environmental Exposure Controls	:	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual Protection Measures

Hygiene Measures	:	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the
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		workstation location.
Eye/face Protection	:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
<u>Skin Protection</u>		
Hand Protection	:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Body Protection	:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other Skin Protection	:	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory Protection	:	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<u>Appearance</u>		
Physical State	:	Liquid [Clear]
Color	:	Clear, colorless to pale yellow, solution
Odor	:	Not Available
Odor Threshold	:	Not Available
pH	:	Not Available
Melting Point	:	Not Available
Boiling Point	:	Not Available
Flash Point	:	Not Available
Evaporation Rate	:	Not Available
Flammability (Solid, gas)	:	Not Available
Lower and Upper Explosive (flammable) limits	:	Not Available
Vapour Pressure	:	Not Available
Vapor Density	:	Not Available
Relative Density	:	Not Available
Solubility	:	Not Available
Partition Coefficient: n-octanol/water	:	Not Available
Auto Ignition Temperature	:	Not Available
Decomposition Temperature	:	Not Available

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Viscosity	:	Not Available
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SECTION 10: STABILITY AND REACTIVITY

Reactivity	:	No specific test data related to reactivity available for this product or its ingredients.
Chemical Stability	:	The product is stable.
Possibility of Hazardous Reactions	:	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to Avoid	:	No Specific Data.
Incompatible Materials	:	Not Available.
Hazardous Decomposition Products	:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute Toxicity	:	There is no data available.
Irritation/Corrosion	:	There is no data available.
Sensitization	:	There is no data available.
Mutagenicity	:	There is no data available.

Carcinogenicity

Classification

Product/Ingredient Name	OSHA	IARC	NTP	ACGIH	EPA	NIOSH
Ethanol	-	1	-	A3	-	-

Reproductive Toxicity	:	There is no data available.
Teratogenicity	:	There is no data available.
Specific Target Organ Toxicity (Single Exposure)	:	There is no data available.
Specific Target Organ Toxicity (Repeated Exposure)	:	There is no data available.
Aspiration Hazard	:	There is no data available.
Information on the likely Routes of Exposure	:	Dermal Contact, Eye Contact, Inhalation, Ingestion.

Potential acute health effects

Eye Contact	:	No known significant effects or critical hazards.
Inhalation	:	No known significant effects or critical hazards.
Skin Contact	:	No known significant effects or critical hazards.
Ingestion	:	No known significant effects or critical hazards.

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Symptoms related to the physical, chemical and toxicological characteristics

Eye Contact	:	No known significant effects or critical hazards.
Inhalation	:	No known significant effects or critical hazards.
Skin Contact	:	No known significant effects or critical hazards.
Ingestion	:	No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short Term Exposure

Potential Immediate Effects	:	No known significant effects or critical hazards.
Potential Delayed Effects	:	No known significant effects or critical hazards.

Long Term Exposure

Potential Immediate Effects	:	No known significant effects or critical hazards.
Potential Delayed Effects	:	No known significant effects or critical hazards.

Potential Chronic Health Effects

General	:	No known significant effects or critical hazards.
Carcinogenicity	:	No known significant effects or critical hazards.
Mutagenicity	:	No known significant effects or critical hazards.
Teratogenicity	:	No known significant effects or critical hazards.
Developmental Effects	:	No known significant effects or critical hazards.
Fertility Effects	:	No known significant effects or critical hazards.

Numerical measures of toxicity

Acute Toxicity Estimates	:	There is no data available.
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SECTION 12: ECOLOGICAL INFORMATION

Toxicity	:	There is no data available.
Persistence And Degradability	:	There is no data available.
Bioaccumulative Potential	:	There is no data available.

Mobility In Soil

Soil/Water Partition Coefficient (K_{OC})	:	Not available.
Other Adverse Effects	:	No known significant effects or critical hazards.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Methods	:	The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a
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	<p>licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.</p>
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SECTION 14: TRANSPORT INFORMATION

	DOT Classification	IMDG	IATA
UN Number	Not regulated.	Not regulated.	Not regulated.
UN Proper Shipping Name	-	-	-
Transport Hazard Class(es)	-	-	-
Packing Group	-	-	-
Environmental Hazards	No.	No.	No.
Additional Information	-	-	-

AERG: Not Applicable

Special Precautions For User	:	<p>Transport Within User's Premises: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.</p>
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SECTION 15: REGULATORY INFORMATION

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

FDA	:	Argatroban Injection is an approved prescription medication.
U.S. Federal Regulations	:	TSCA 8(a) CDR Exempt/Partial Exemption: Not Determined United States Inventory (TSCA 8b): Not Determined.
Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)	:	Not listed.
Clean Air Act Section 602 Class I Substances	:	Not listed.
Clean Air Act Section 602 Class II Substances	:	Not listed.
DEA List I Chemicals (Precursor Chemicals)	:	Not listed.
DEA List II Chemicals (Essential Chemicals)	:	Not listed.
SARA 302/304		
Composition/Information On	:	No products were found.

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Ingredients		
SARA 304 RQ	:	Not Applicable
<u>SARA 311/312</u>		
Classification	:	Not Applicable
SARA 313	:	There is no data available.
<u>State Regulations</u>		
Massachusetts		None of the components are listed.
New York		None of the components are listed.
New Jersey		The following components are listed: Ethanol
Pennsylvania		The following components are listed: Ethanol
<u>California Prop. 65</u>		
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.		

SECTION 16: OTHER INFORMATION

Procedure Used To Derive the Classification:

Classification	Justification
Not Classified	-

History:

Issued Date	:	03.02.21
Revision Date	:	Nil
Version	:	00

Notice to Reader

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 the accuracy or completeness of the information contained 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.

----End of SDS---