

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	ARGATROBAN INJECTION
Synonyms	ARGATROBAN INJECTION CONCENTRATE 100 MG/ML * SKF-105043, FORMULATED PRODUCT * NDC NO. 0007-4407-01 * ARGATROBAN, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
ARGATROBAN, BULK ACTIVE	74863-84-6	10
ETHANOL	64-17-5	38
NON-HAZARDOUS INGREDIENTS	Unassigned	52

3. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as flammable.
Health	<p>Caution - Pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. Eye irritant. Possible effects of overexposure in the workplace include: reduced blood coagulation. Health effects information is based on hazards of components.</p>
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of anti-coagulant. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	This product is flammable. Fire and explosions might result if vapours are allowed to accumulate in the vicinity of a source of ignition.
Extinguishing Media	Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal. Move containers from the fire area if possible without increased personal risk.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.
Environmental Precautions	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal. Equipment used for clean-up should be earthed (grounded) and non-sparking.

Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product. Detergent solutions can be used for clean-up and decontamination operations.
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7. HANDLING AND STORAGE

HANDLING

General Requirements This material contains flammable components. Ensure that any area in which this material is handled has sufficient ventilation to avoid the build up of vapour and to control employee potential exposure to volatiles below National Occupational Exposure Limits.

Ignition Controls Avoid contact with ignition sources. This liquid might ignite in contact with some types of ignition source.

STORAGE Keep in tightly sealed containers or packages in a well-ventilated area. No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. Keep away from sources of ignition.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT ARGATROBAN, BULK ACTIVE

GSK Occupational Hazard Category 3

GSK Occupational Exposure Limit 80 mcg/m³ (8 HR TWA)

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection Wear approved safety glasses with side shields or cover goggles if eye contact is possible.

Other Equipment or Procedures An eye wash station should be available. Wear appropriate clothing to avoid skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity Clear.

Colour Colourless/light yellow.

Physical Form Liquid.

Packaging Vial.

Flash Point 27 to 28 °C (Estimation based on components).

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid Avoid direct sunlight, conditions that might generate heat and sources of ignition.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation might occur following direct contact with eyes.

Target Organ Effects No specific target organ effects have been identified.

Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a thrombin inhibitor.
Other Adverse Effects	Overexposure in the workplace might have the following effects: impaired blood coagulation.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1000 mg/l, 3 Hours, Activated sludge, Nominal

NOEC: 1000 mg/l, 3 Hours

Algal This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 100 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Measured

NOEL: 100 mg/l, 72 Hours

*** Daphnid** This material contains an active pharmaceutical ingredient that is harmful to daphnids.

EC50: 52 mg/l, 48 Hours, Daphnia magna, Measured

NOEL: 5.6 mg/l, 48 Hours

Fish This material contains an active pharmaceutical ingredient that is not toxic to fish.

Juvenile Oncorhynchus mykiss, rainbow trout

EC50: > 100 mg/l, 96 Hours, Measured

NOEL: 100 mg/l, 96 Hours

MOBILITY

Partitioning

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

Aerobic - Inherent

Percent Degradation: 10 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge

Percent Degradation: 8 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

13. DISPOSAL CONSIDERATIONS

Disposal**Recommendations**

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Technical Name	ARGATROBAN INJECTION
Proper Shipping Name	Ethanol Solution
UN Number	UN 1170
Class/Division	3
Packing Group	III
Risk Label(s)	Class 3 Flammable Liquid

**International Air Transport (IATA Requirements)**

Classification and Labelling As UN Classification and Labelling above

International Maritime Transport (IMDG Requirements)

Classification and Labelling As UN Classification and Labelling above

US Domestic Transport (DOT Requirements)

Classification and Labelling This product is exempt from US DOT requirements under exemption DOT-E9275. Reference to this exemption should be included on the packaging and shipping papers for transportation in the US. In case of loss of contents the carrier must immediately notify GlaxoSmithKline using the telephone numbers in Section 1 of the MSDS.

European Ground Transport (ADR/RID Requirements)

Classification and Labelling Not subject to ADR, see SP 601.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.
For waste disposal purpose, this product should be classified in line with the European Waste Catalogue criteria.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 25-Jan-2007

SDS Version Number 15

SDS Sections Updated

Sections

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY
REGULATORY INFORMATION
TRANSPORT INFORMATION

Subsections

US Environmental (EPA) Requirements

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.