

# Safety Data Sheet (US)

Federal Hazard Communication Standard (29 CFR 1910.1200)

Date of issue: 09-APR-2018

Replaces version of:

ARGATROBAN



## Section 1: Identification

<b>Product name</b>	ARGATROBAN
<b>Chemical Name</b>	ARGATROBAN
<b>Synonyms</b>	1-[5-[(AMINOIMINOMETHYL)AMINO]-1-OXO-2-[[[1,2,3,4-TETRAHYDRO-3-METHYL-8-QUINOLINYL]SULFONYL]AMINO]PENTYL]-4-METHYL-2-PIPERIDINECARBOXYLIC ACID, ARGATROBAN
<b>CAS Number</b>	74863-84-6
<b>Usage</b>	Pharmaceutical active ingredient
<b>Company name</b>	Novartis Pharma AG 4002 Basel Switzerland Tel: +41 61 324 11 11, email: sds.support@novartis.com
<b>Emergency phone number</b>	CHEMTEL (International) +1 813 676 1670 (365/24/7)

## Section 2: Hazards identification

### GHS hazard category

Acute Toxicity (oral): not classified

Skin Corrosion / Irritation: not classified

Eye Corrosion / Irritation: not classified

Skin sensitizer: not classified

Germ cell mutation: not classified

Reproductive toxicity: not classified

Explosives, oxidizing, self-reactive or self-heating, pyrophoric substances, substances which in contact with water emit flammable gases, organic peroxides: not classified

Acute aquatic toxicity: Cat.3

Chronic aquatic toxicity: Cat.3

**Signal Word:** Self assessment according REGULATION (EC) No 1272/2008

**Hazard statements** H402: Harmful to aquatic life.(in EU not leading to classification as hazardous)

H412: Harmful to aquatic life with long lasting effects.

**Precautionary statements** P273: Avoid release to the environment.

### Other hazards

**Specific hazards** None known

## Section 3: Composition / information on ingredients

### Chemical characterisation of the substance / preparation:

<b>Type</b>	Substance
<b>Chemical Name</b>	ARGATROBAN
<b>CAS Number</b>	74863-84-6

For TLV values of declared components, see Section 8, Exposure controls / Personal

Full text of H-Phrases see under Section 16

## Section 4: First aid measures

**Inhalation** After inhalation move to fresh air. If shortness of breath occurs, support respiration and consult a physician.  
Bring patient immediately to fresh air. If breathing is heavily give oxygen; if necessary respiration artificially. Call physician.

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Consult a physician if irritating symptoms develop and persist.

**Skin Contact** Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.

**Eye Contact** Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).

**Ingestion** Do not induce vomiting. In case of consciousness wash mouth with water and let drink some of water. Seek medical advice. Keep patient at rest. If swallowed, seek medical advice immediately and show this container or label.

## Self-protection of the first aider

For personal protection see Section 8

**Notes to Physician** Apply general supportive and symptomatic treatment.

## Section 5: Fire fighting measures

**Suitable Extinguishing Media** Water spray or fog, foam, dry chemical powder, CO2, dry sand

**Unsuitable Extinguishing Media** No restrictions

**Dangerous Combustion Products** carbon oxides  
nitrogen oxides  
sulfur oxides

**Protective equipment for firefighters** Wear self-contained breathing apparatus and fire protective suite.

## Section 6: Accidental release measures

**Personal precautions** Avoid contact with skin, eyes and clothing.

**Environmental precautions** Must not be released into sewers, drains or wells.

**Methods for cleaning** Transfer large quantities into a container, rinse the rest with plenty of water.

For personal protection see Section 8, for disposal considerations see Section 13

## Section 7: Handling and storage

**Storage and Handling Precautions** Open handling without suitable personal protective equipment must be avoided. Keep container tightly closed in a dry, cool and well-ventilated place. Ensure efficient exhaust ventilation when using this product

For Industrial Hygiene Measures see Section 8, Exposure controls / Personal protection

**Technical measures/ Precautions** Handle product only in closed system or provide appropriate exhaust ventilation at machinery.

**Preventive Precautions (fire/explosion)** Take precautionary measures against static discharges. Avoid formation of dust. Keep away from sources of ignition. Observe the usual precautionary measures required for chemicals with dust explosive properties (Observe national regulations).

## Section 8: Exposure controls / Personal protection

### Control parameters

List type	Value	Unit	
Occupational Exposure Limit (OEL)	200	µg/m3	HHA Database

### Exposure Controls

**Industrial Hygiene** The personal protective measure may be adapted appropriately when working in closed

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systems or under laboratory conditions.  
Regular cleaning of equipment, work area and clothing.  
Open handling at operator intervention points with local exhaust ventilation (e.g. downflow booths).  
Internal working procedures available to personnel covering personal hygiene, standard cleaning, waste disposal and maintenance.  
Personnel instructed and trained, regular refresher training established.  
Double wardrobe must be available.

## Open Handling

Respiration : If the Breathing Zone sampling results exceed the established occupational exposure limit (OEL) or the minimum concentration defined by the occupational hazard band, use respiratory protection with sufficient protection factor to ensure exposure is below the exposure limit. Unless the exposure results indicate the requirement for an air supplied device, use HEPA filters for powders or aerosols and cartridge or canister filters for vapors and gases.

Filter : P3 (EN143)

Eye : Safety glasses (EN166)

Hand : Normal length chemical-mechanical resistant gloves (EN374/EN388)

Glove Material : Nitrile  
Breakthrough time: 240 min  
Thickness: 0.4 mm

Additional protection : working clothes (EN 340)

These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the officially tested permeation time.

## Section 9: Physical and chemical properties

<b>Formulation</b>	powder
<b>Physical state</b>	solid
<b>Colour</b>	white
<b>Odour</b>	no data available
<b>Odour threshold</b>	no data available
<b>pH</b>	not available
<b>Melting point/range</b>	no data available
<b>Boiling Point</b>	no data available
<b>Flash Point</b>	not applicable
<b>Evaporation Rate (Ref: Ether)</b>	not applicable
<b>Combustibility Test</b>	no data available
<b>Explosion Limits</b>	not applicable
<b>Vapour Pressure [hPa]</b>	not applicable
<b>Vapour Density</b>	not applicable
<b>Density</b>	no data available
<b>Solubility (Aqueous Solvents)</b>	no data available
<b>Solubility (Solvents)</b>	no data available
<b>Partition Coefficient</b>	log Pow: 2.05 Method: (calculated)
<b>Autoignition/MIT</b>	no data available
<b>Dynamic Decomposition</b>	no data available
<b>Isoperibolic Decomposition (&gt;8h)</b>	no data available

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**Viscosity** not applicable  
**Explosivity/Reactivity** no data available  
**Test for self-heating** no data available  
**Fire-promoting properties** no data available

## Other information

**Dust Explosion** Minimum Ignition Energy: 90 - 100 mJ  
**Specific Resistivity**  $4 * 10E14$  Ohm m (humidity: 58 %, Temperature: 21 °C)

## Section 10: Stability and reactivity

**Reaction products with water** None known

**Hydrolysis** : no data available

### Possibility of hazardous reactions

**Materials to avoid** strong oxidizing agents

### Conditions to avoid

**Conditions to avoid** Keep away from open flames, hot surfaces and sources of ignition.

### Hazardous Decomposition Products

**Hazardous Decomposition Products** None, when used and handled as intended.

## Section 11: Toxicological information

**Acute Toxicity** LD50: > 15000 mg/kg  
Route: oral  
Species: rat

**Irritation, Corrosion** May cause irritation of the mucous membranes.  
Eyes non irritant  
Skin (Species: rabbit) non irritant  
Eyes (Species: rabbit) non irritant  
Method: OECD Guideline 405 (Acute Eye Irritation / Corrosion)  
Skin (Species: rabbit) non irritant  
Method: OECD Guideline 405 (Acute Eye Irritation / Corrosion)

**Sensitisation** Skin (Species: mouse) not sensitizing  
Method: OECD Guideline 429 (Skin Sensitisation - LLNA)  
Skin (Species: mouse) not sensitizing  
Method: OECD Guideline 406 (Skin Sensitisation)

**Mutagenicity** Negative (AMES-Test (reverse mutation assay))  
in vitro  
Information from other sources (e.g. literature)  
Negative (Chromosome Aberration Study)  
in vivo, Species: chinese hamster  
Information from other sources (e.g. literature)  
Negative (Mammalian Cell Mutagenicity Test(HGPRT))  
Information from other sources (e.g. literature)  
Negative (Micronucleus Test)  
in vivo, Species: mouse  
Information from other sources (e.g. literature)  
Negative (Unscheduled DNA Synthesis)

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in vitro  
Information from other sources (e.g. literature)  
Negative (Unscheduled DNA Synthesis)  
in vivo  
Information from other sources (e.g. literature)  
Negative with and without metabolic activation (AMES-Test (reverse mutation assay))  
in vitroCell: Strains of Salmonella typhimurium and Escherichia coli.  
Negative (Chromosome Aberration Study)  
in vitroCell: Chinese hamster ovary (CHO) cells  
Negative (Micronucleus Test)  
intravenous, Species: mouse, Cell: Bone marrow

## Chronic Effects

no data available  
Minimal toxicity - reversible (Repeated Dose Toxicity (chronic Toxicity))  
NOAEL: = 9 mg/kg/d  
Route: intravenous  
Species: rat, Organ: Blood  
Duration: = 6 months  
No findings (Repeated Dose Toxicity (subacute study))  
NOEL: = 30 mg/kg/d  
Route: intravenous  
Species: dog  
Duration: = 28 days  
No findings (Repeated Dose Toxicity (subacute study))  
NOEL: = 60 mg/kg/d  
Route: intravenous  
Species: dog  
Duration: = 1 months  
Slight toxicity - reversible (Repeated Dose Toxicity (chronic Toxicity))  
NOAEL: = 1 mg/kg/d  
Route: intravenous  
Species: dog  
Duration: = 6 months

## Reproduction Toxicity

(Embryo-Fetal Development)  
NOAEL: 27 mg/kg/d  
Route: intravenous  
Species: rat  
(Embryo-Fetal Development)  
NOAEL: 10.8 mg/kg/d  
Route: intravenous  
Species: rabbit  
(Effect on fertility.)  
NOAEL: 27 mg/kg/d  
Route: intravenous  
Species: rat  
NO FERTILITY EFFECTS (Fertility and early Embryonic Development)  
NOEL: 9 mg/kg/d  
Route: intravenous  
Species: rat  
Negative (Embryo-Fetal Development)  
Route: intravenous  
Species: rat  
No Teratogenicity (Embryo-Fetal Development)  
NOEL: 0.5 mg/kg/d  
NOEL: 1 mg/kg/d  
Route: intravenous  
Species: rabbit

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Maternal toxicity (Peri- and Postnatal Development)  
NOEL: 9 mg/kg/d  
Route: intravenous  
Species: rat

## Toxicological Hazard Classification

**Acute Toxicity (oral):** not classified  
**Acute Toxicity (dermal):** not classifiable  
**Acute Toxicity (inhalation):** not classifiable  
**Eye Corrosion / Irritation:** not classified  
**Skin Corrosion / Irritation:** not classified  
**Respiratory sensitizer:** not classifiable  
**Skin sensitizer:** not classified  
**Germ cell mutation:** not classified  
**Carcinogenicity:** not classifiable  
**Reproductive toxicity:** not classified  
**Specific organ toxicity (single dose), not lethal:** not classifiable  
**Specific organ toxicity (repeated exposure):** not classifiable  
**Aspiration Hazard:** not applicable

## Carcinogenicity listing

**Public Lists (International)** International Lists: Not Listed

## Section 12: Ecological information

**Ecotoxicity Summary** Avoid release to the environment.  
Bioaccumulation in water organisms is not likely based on the n-octanol/water partition coefficient ( $\log P_{ow} < 3.0$ ).

**Fish acute toxicity** EC50: > 100 mg/l  
NOEC: 100 mg/l  
Species: rainbow trout (*salmo gairdneri*, *oncorhynchus mykiss*)  
Exp. time: 96 hours

**Aquatic invertebrate acute toxicity** NOEC: 5.6 mg/l  
EC50: 52 mg/l  
Species: *daphnia magna* (water flea)  
Exp. time: 48 hours

**Algae Toxicity** EC50: > 100 mg/l  
NOEC: 100 mg/l  
Species: *Scenedesmus subspicatus*  
Exp. time: 72 hours

**Bacterial Respiration Inhibition** NOEC: 1000 mg/l  
IC50: > 1000 mg/l  
Species: activated sludge  
Exp. time: 3 hours  
Nominal values

**Biological Elimination** Degradation: 10 % ( DOC)  
Little or no biodegradation  
Method: ECT-OECD 302B (Zahn-Wellens mod.by ECT)

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<b>Partition Coefficient</b>	log Pow: 2.05 Method: (calculated)
<b>Biological accumulation</b>	no data available
<b>Soil and Sludge Sorption/Desorption</b>	no data available
<b>PBT assessment</b>	According to REACH legislation no PBT, vPvB substance.
<b>Other adverse effects</b>	no data available

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## Section 13: Disposal considerations

**Disposal Requirements** Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control.

**Container Disposal** For disposal local regulation is binding.

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## Section 14: Transport information

Regulation	IMDG-Code:	ICAO/IATA-DGR:
UN Number	0	0
UN Proper Shipping Name	-	-
Transport Hazard Class(es)		
Transport Label(s)		
Packing group		
Environmental Hazard		
Additional Information		

### *Special Precaution for User*

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.

**Temperature Conditions for Transport** Undefined

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## Section 15: Regulatory information

International Lists: Not Listed

**Toxic Substances Control Act** Not listed or exempted

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## Section 16: Other information

**Abbreviations used**

**Recipient**

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.