Issue date: 11-May-2015 Revision date: 11-May-2015 Version number: 17





1. Identification

Product identifier ARGATROBAN INJECTION

Other means of identification

Synonyms ARGATROBAN INJECTION CONCENTRATE 100 MG/ML * ARGATROBAN, FORMULATED

PRODUCT * SKF-105043, FORMULATED PRODUCT * NDC NO. 0007-4407-01

Recommended use of the chemical and restrictions on use

Recommended use Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia 1061 Mountain Highway Melbourne, Victoria 3155

Australia

Australia General Information (Normal Business Hours): (03) 9721 6000

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TRANSPORTATION EMERGENCY NUMBERS (available 24hrs/7days: multi-language response)

Australia Toll Free +(61) 2 9037 2994 International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture

| Identity of chemical ingredients | CAS number and other unique identifiers | Concentration of ingredients | |
|----------------------------------|---|------------------------------|--|
| ETHANOL | 64-17-5 | 38 | |

ALCOHOL ANHYDROUS
ANHYDROUS ETHANOL
ANHYDROUS ETHYL ALCOHOL
ETHANOL 200 PROOF
Ethyl alcohol
ETHYL ALCOHOL USP 200 PROOF (USI)
ETHYL ALCOHOL, 100%
ETHYL HYDROXIDE
GRAIN ALCOHOL
ETHANOL

ARGATROBAN, BULK ACTIVE

74863-84-6

10

SKF-105043

(2R,4R)-4-METHYL-1-[N2-(3-METHYL-1,2,3,4-TETRAHYDRO-8-QUINOLINE

SULFONYL)-L- ARGINYL]-2-PIPERIDINECARBOXYLIC ACID

1-[5-[AMINOIMINOMETHYL)AMINO]-1-OXO-2-[[1,2,3,4-TETRAHYDRO-3-ME

THYL-8-QUINO

LINYL)SULFONYLJAMINOJPENTYLJ-4-METHYL-2-PIPERIDINECARBOXYLIC

ACID

Other components below reportable levels

52

4. First-aid measures

Description of necessary first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control centre immediately. Do not induce vomiting without

advice from poison control center.

Personal protection for first-aid

responders

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take

precautions to protect themselves.

Symptoms caused by exposure

Medical attention and special

treatment

Direct contact with eyes may cause temporary irritation.

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

information centre.

Water.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing

media

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire

fighters

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

Hazchem Code Not available.

General fire hazards Flammable liquid and vapour.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency

personnel

Keep unnecessary personnel away. Keep upwind. Keep out of low areas. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during

clean-up. Use personal protection recommended in Section 8 of the SDS.

Avoid discharge into drains, water courses or onto the ground. **Environmental precautions**

Material name: ARGATROBAN INJECTION

Methods and materials for containment and cleaning up

Keep combustibles (wood, paper, oil etc) away from spilled material.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling

Keep away from sources of ignition - No smoking. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. When using do not smoke. Avoid breathing mist or vapour. Avoid contact with eyes. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. Store away from incompatible materials (see Section 10 of the SDS).

1000 ppm

8. Exposure controls and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

| Components | Туре | Value |
|--------------------------------|----------|-----------|
| ARGATROBAN (CAS 74863-84-6) | 8 HR TWA | 80 mcg/m3 |
| , | OHC | 3 |

| Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A) | | | |
|---|------|------------|--|
| Components | Туре | Value | |
| ETHANOL (CAS 64-17-5) | TWA | 1880 mg/m3 | |

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational

| Components | Туре | Value |
|-----------------------|------|------------------------|
| ETHANOL (CAS 64-17-5) | TWA | 1880 mg/m3 1000 ppm |

US. ACGIH Threshold Limit Values

| Туре | Value | | |
|---|-----------------------------|--------------------------------------|--|
| STEL | 1000 ppm | | |
| UK. EH40 Workplace Exposure Limits (WELs) | | | |
| Туре | Value | | |
| TWA | 1920 mg/m3 | | |
| | STEL mits (WELs) Type | STEL 1000 ppm mits (WELs) Type Value | |

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

| Components | Туре | Value | |
|-----------------------|------|-----------|--|
| ETHANOL (CAS 64-17-5) | TWA | 960 mg/m3 | |
| | | 500 ppm | |

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering

controls

General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

If contact is likely, safety glasses with side shields are recommended. Eye/face protection

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves.

Other Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate

certified respirators.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material

and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance

from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Liquid. Form Vial.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling

range

> 79 °C (> 174.2 °F) (Estimation based on components).

Flash point 26 °C (78.8 °F) Closed cup (Estimation based on components).

Evaporation rate Not available.
Flammability (solid, gas) Not available.
Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper Not available.

(%)

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the

flash point. Contact with incompatible materials.

Incompatible materials Strong oxidising agents.

Material name: ARGATROBAN INJECTION

Hazardous decomposition

products

None known. Irritating and/or toxic fumes and gases may be emitted upon the product's

decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Health injuries are not known or expected under normal use.

Eve contact Causes serious eve irritation.

Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed.

However, ingestion is not likely to be a primary route of occupational exposure.

Direct contact with eyes may cause temporary irritation. Symptoms related to exposure

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Test results Components **Species**

ARGATROBAN, BULK ACTIVE (CAS 74863-84-6)

Acute

Oral

LD50 Rat > 15000 mg/kg

ETHANOL (CAS 64-17-5)

Acute Oral

LD50

Rat > 2000 mg/kg

Chronic

Oral

LOAEL Monkey 40 %, 48 months % ingested calories

Subacute

Oral

LOEL Rat 16.9 g/kg, 4 weeks Dietary - Dose given as

g/kg/day

6 %, 4 weeks percent in diet - continuous

Subchronic

Inhalation

LOEL Rat 2 ml, 36 weeks haematological parameters

NOAEL Guinea pig 3000 ppm No adverse effects 86 mg/m3, 90 Day Daily dosing

Rat

Oral

LOAEL Rat 5000 mg/kg/day, 10 weeks Liver toxicity

80 ml/kg, 85 Day Daily dose - Liver toxicity

10.2 g/kg, 12 weeks Dosed in drinking

water - Continuous

7.7 g/kg, 12 weeks Dosed in drinking water

- continuous

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

ETHANOL OECD 404

Result: Negative; not considered a significant irritant

Species: Rabbit

Irritation Corrosion - Skin

ARGATROBAN, BULK ACTIVE Acute dermal irritation; OECD 404, Primary Irritation Index: 0

Result: negative

Species: Rabbit

Causes serious eye irritation. Serious eye damage/irritation

Material name: ARGATROBAN INJECTION

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^{*} Estimates for product may be based on additional component data not shown.

Eye

ARGATROBAN, BULK ACTIVE IRE Assay

Result: Negative; not likely to be a severe irritant OECD 405

Result: Severe Species: Rabbit

Respiratory or skin sensitisation

Skin sensitisation This product is not expected to cause skin sensitisation.

Sensitisation

ARGATROBAN, BULK ACTIVE Local lymph node assay, Maximum concentration = 25%;

vehicle = DMF Result: negative Species: Mouse OECD 406

ETHANOL OECD 406
Result: negative

Species: Guinea pig

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Mutagenicity

ETHANOL Ames

Result: negative

ARGATROBAN, BULK ACTIVE Ames Assay, Literature data

Result: negative

ETHANOL Chromosomal Aberration Assay In Vitro, CHO cells

Result: negative

ARGATROBAN, BULK ACTIVE Chromosomal aberration assay - Chinese hamster lung

fibroblasts, Literature data

Result: negative
ETHANOL Dominant lethal assay

Result: positive Species: Mouse Dominant lethal assay Result: positive Species: Rat

Gene mutation and repair

Result: negative Species: Bacteria Gene mutation and repair

Result: positive Species: Bacteria

In vitro cytogenetics assay

Result: positive

In vitro cytogenetics assay

Result: positive

Species: Aspergillus niger

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Weakly positive

ARGATROBAN, BULK ACTIVE Mammalian cell mutation assay (CHO/HGPRT forward

mutation assay), Literature data

Result: negative

Micronucleus Assay, Literature data

Result: negative Species: Mouse

Unscheduled DNA Synthesis in vitro (WI-38 lung fibroblasts),

Literature data Result: negative

Unscheduled DNA Synthesis, in vivo - in vitro (hepatocytes),

Literature data Result: negative Yeast mutation

Result: negative

Result: negative Yeast mutation Result: positive

in vitro micronucleus assay

Result: negative

Material name: ARGATROBAN INJECTION

ETHANOL

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Mutagenicity

ETHANOL in vivo cytogenetics assay

Result: negative Species: Hamster

in vivo cytogenetics assay

Result: negative Species: Rat

in vivo cytogenetics assay

Result: positive Species: Mouse

sister chromatid exchange

Result: positive

Carcinogenicity ETHANOL Carcinogenic effects are not expected as a result of occupational exposure.

0, inadequate study

Result: Increase in liver sarcomas

Species: Mouse 0, inadequate study

Result: Time to tumour reduced

Species: Mouse Test Duration: 80 weeks 0, inadequate study Result: negative Species: Hamster Test Duration: 807 Day 0, inadequate study Result: negative Species: Mouse

Test Duration: 1020 Day 0, inadequate study Result: negative Species: Rat 0, inadequate study Result: negative Species: Rat

Test Duration: 78 weeks

Epidemiology, causation linked to excessive consumption.

Species: Human

Organ: oral cavity, larynx, pharynx, oesophagus, liver

Neonatal, inadequate study

Result: negative Species: Rat

Reproductive toxicityThis product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

May cause drowsiness and dizziness.

Specific target organ toxicity - repeated exposure

Not classified.

Aspiration hazard Not established.

Chronic effects Prolonged inhalation may be harmful.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause

adverse effects.

12. Ecological information

EcotoxicityThe product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components Species Test results

ARGATROBAN, BULK ACTIVE (CAS 74863-84-6)

Acute

IC50 Activated sludge > 1000 mg/l, 3 hours Nominal

NOEC Activated sludge 1000 mg/l, 3 hours

Material name: ARGATROBAN INJECTION

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| Components | | Species | Test results |
|-----------------------|------|---|--|
| Aquatic | | | |
| Acute | | | |
| Algae | EC50 | Green algae (Scenedesmus subspicatus) | > 100 mg/l, 72 hours Measured |
| | NOEC | Algae | 100 mg/l, 72 hours |
| Crustacea | EC50 | Water flea (Daphnia magna) | 52 mg/l, 48 hours Measured |
| | NOEC | Daphnia | 5.6 mg/l, 48 hours |
| Fish | EC50 | Rainbow trout (Juvenile Oncorhyncus mykiss) | > 100 mg/l, 96 hours Measured |
| | NOEC | Rainbow trout (Juvenile Oncorhyncus mykiss) | 100 mg/l, 96 hours |
| ETHANOL (CAS 64-17-5) | | | |
| Aquatic | | | |
| Acute | | | |
| Algae | EC50 | Blue-green algae (Microcystis aeruginosa) | 1450 mg/l, 72 hours |
| Crustacea | EC50 | Water flea (Daphnia magna) | 9190 mg/l, 48 hours Static test |
| Fish | EC50 | Fathead minnow (Adult Pimephales promelas) | 14200 mg/l, 96 hours Flow-through test |
| | | Rainbow trout (Adult Salmo gairdneri) | 13000 mg/l, 96 hours Static test |

^{*} Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ETHANOL 1 - 36.6 years Measured

Half-life (Photolysis-atmospheric)

ETHANOL 4 - 5.9 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ARGATROBAN, BULK ACTIVE 10 %, 28 days Modified Zahn-Wellens, DOC removal.,

Activated sludge

8 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge 37 - 86 %, 5 days BOD5, Activated sludge

ETHANOL Bioaccumulative potential

Partition coefficient

n-octanol / water (log Kow)

ARGATROBAN, BULK ACTIVE 2.05 (Calculated).

ETHANOL -0.31

Mobility in soil No data available for this product.

Adsorption

Soil/sediment sorption - log Koc

ETHANOL 1.2 Calculated

Mobility in general

Volatility

Henry's law

ETHANOL 0.000005 atm m3/mol Measured

Other adverse effects Not available.

13. Disposal considerations

Disposal methodsCollect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not

discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable

regulations.

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some

product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions). Avoid discharge into water courses or onto the ground.

Empty containers should be taken to an approved waste handling site for recycling or disposal. Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

ADG

1170 **UN number**

ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) **UN proper shipping name**

Transport hazard class(es)

Class 3 Subsidiary risk Ш Packing group

Environmental hazards Not available.

Hazchem Code •2YE

Special precautions for user Not available.

IATA

1170 **UN** number

UN proper shipping name Transport hazard class(es) Ethanol solution

3 Class Subsidiary risk Packing group Ш **Environmental hazards** No. 3L **ERG Code**

Special precautions for user Not available.

Other information

Passenger and cargo Allowed.

aircraft

Cargo aircraft only Allowed.

IMDG

UN number 1170

ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION) **UN** proper shipping name

(ARGATROBAN INJECTION)

Transport hazard class(es)

Class 3 Subsidiary risk Label(s) 3 Ш Packing group

Environmental hazards

Marine pollutant No. F-E, S-D **EmS** Special precautions for user Not available.

Transport in bulk according to

Not available.

Annex II of MARPOL 73/78 and

the IBC Code

ADG



IATA; IMDG



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

15. Regulatory information

Safety, health and environmental regulations

National regulations

This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

ETHANOL (CAS 64-17-5)

Low toxicity. General: Any use

Use pattern restricts hazard. Human therapeutic use

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

stralia Medicines & Poisons Schedule 6

Poisons schedule number not allocated. **Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

ETHANOL (CAS 64-17-5) 10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

ETHANOL (CAS 64-17-5) 10000 - 99999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 11-May-2015
Revision date 11-May-2015

References GSK Hazard Determination

Material name: ARGATROBAN INJECTION

Disclaimer

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.

Revision Information

Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Ingredients

Exposure Controls / Personal Protection:
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Genetic Tox and Carcinogen

Ecological Information: Ecotoxicity

Transport Information: Proper Shipping Name/Packing Group

Material name: ARGATROBAN INJECTION

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