SAFETY DATA SHEET

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

Material ARIXTRA INJECTION

ARIXTRA INJECTION 2.5 MG/0.5 ML * ARIXTRA INJECTION 5 MG/0.4 ML *

Synonyms

ARIXTRA INJECTION 7.5 MG/0.6 ML * ARIXTRA INJECTION 10 MG/0.8 ML *

NDC 66203-2300-02 * NDC 0007-3232-11 * NDC 0007-3234-11 * NDC

0007-3236-11 * FONDAPARINUX SODIUM, FORMULATED PRODUCT

GlaxoSmithKline, Corporate Environment, Health & Safety

Company Name

980 Great West Road

Brentford, Middlesex TW8 9GS UK

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

GlaxoSmithKline, Corporate Environment, Health & Safety

2200 Renaissance Blvd, Suite 105

King of Prussia, PA 19406 US

US General Information: +1-888-825-5249

Transport Emergency (non EU) +1-703-527-3887

US number, available 24 hours

Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Percentage

Ingredients CAS RN

FONDAPARINUX SODIUM 0.5

114870-03-0

NON-HAZARDOUS INGREDIENTS 99.5

Unassigned

3. HAZARDS IDENTIFICATION

Expected to be non-combustible.

Fire and Explosion

Health Caution - Pharmaceutical agent.

Exposure might occur via inhalation; skin; eyes.

Possible effects of overexposure in the workplace include: bleeding.
Health effects information is based on hazards of components.
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 current prescribing information or to the local poison control information centre.
Medical Conditions None for occupational exposure.
Caused or Aggravated by Exposure
Antidotes No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion This product is non-combustible, although the packaging is combustible.
Hazards
Special Firefighting For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or
Procedures
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.
Hazardous Combustion Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.
Products

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Wear protective clothing and equipment consistent with the degree of hazard.
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.
Decontamination No specific decontamination or detoxification procedures have been identified for this product.
Procedures

7. HANDLING AND STORAGE

HANDLING

General Requirements No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
STORAGE No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION
FONDAPARINUX SODIUM
INGREDIENT
3
GSK Occupational
Hazard Category
Other Equipment or Wash hands and arms thoroughly after handling. Wear appropriate clothing to avoid skin contact.
Procedures

9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance
Clear.
Clarity
Colourless.
Colour
Liquid.
Physical Form

10. STABILITY AND REACTIVITY
Stability DO NOT FREEZE - dispose of properly if frozen.
Conditions to Avoid None for normal handling of this product.

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 is not expected 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 product contains active ingredient(s) with the following activity: reduced blood coagulation.
Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

* Summary This material contains an active pharmaceutical ingredient that has had limited testing and no adverse environmental effects were observed in the tests conducted. This material is not expected to persist in 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

* Microbial Growth This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

Inhibition

Minimum Inhibition > 1000 mg/l

Concentration:

MOBILITY
* Solubility This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
* Volatility This material contains an active pharmaceutical ingredient that will not readily enter into air from water.
Henry's Law Constant > 9.67E+00 atm m^3/mol, Calculated
* 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
* Hydrolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.
Half-Life, Neutral: > 1 Years, Measured, pH 7 Buffer Solution
* Biodegradation This material is likely to rapidly undergo biotransformation by microorganisms. This material is likely to undergo mineralization by microorganisms.

13. DISPOSAL CONSIDERATIONS

Disposal Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or
Recommendations
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
Transportation and shipping of this product is not restricted. It has no known,
Transport Information
significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

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.

US OSHA Standard (29 CFR Part 1910.1200)

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

Target Organ No specific target organ effects known.

Statement

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Number 128982 Approved/Revised 10-May-2005 Version 03
Material ARIXTRA INJECTION

Date Approved/Revised 10-May-2005 SDS Version Number 3

SDS Sections Updated
Sections Subsections
ECOLOGICAL INFORMATION Activated Sludge Respiration
Adsorption
Algal
Algal Degradation
Bioaccumulation
Biodegradation
Daphnid
Distribution
Earthworm
Ecotoxicity
Fish
Hydrolysis
Microbial Growth Inhibition
Microtox
Mobility
Other Adverse Effects
Other Species - Aquatic
Other Species - Terrestrial
Partitioning
Persistence/Degradation
Photolysis
Solubility
Summary
Volatility
TOXICOLOGY INFORMATION Genetic Toxicity
Reproductive Effects