



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>ARIXTRA INJECTION</b>
<b>Other means of identification</b>	Not available.
<b>Synonym(s)</b>	ARIXTRA INJECTION 2.5 MG/0.5 ML * ARIXTRA INJECTION 5 MG/0.4 ML * ARIXTRA INJECTION 7.5 MG/0.6 ML * ARIXTRA INJECTION 10 MG/0.8 ML * NDC NO. 0007-3230-02 * NDC NO. 0007-3232-11 * NDC NO. 0007-3234-11 * NDC NO. 0007-3236-11 * FONDAPARINUX SODIUM, FORMULATED PRODUCT
<b>Recommended use</b>	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.
<b>Recommended restrictions</b>	No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

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

### Label elements

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

### Hazard(s) not otherwise classified (HNOC)

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

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
FONDAPARINUX SODIUM	METHYL O-(2-DEOXY-6-O-SULFO-2-SULFOAMINO- ALPHA-D-GLUCOPYRANOSYL)-(1-4)-O-(B ETA-D-GLUCOPYRANOSYL)-3,6-DI-O-SULFO- 2-SULFOAMINO-ALPHA-D-GLUCOPYRANO SYL)(1-4)-O-(2-O-SULFO-ALPHA-LIDOPYR ANURONOSYL)-2-DEOXY-6-O-SULFO-2-SULF OAMINO-ALPHA-D GLUCOPYRANOSIDE, DECASODIUM SALT PENTASACCHARIDE POLYSULFATED DECASODIUM SALT ALPHA-D-GLUCOPYRANOSIDE, METHYL O-2-DEOXY-6-O-SULFO-2-(SULFOAMINO)- ALPHA-D-GLUCOPYRANOSYL-(1-4)-O-BE TA-D-GLUCOPYRANURONOSYL-(1-4)-O-2- DEOXY-3,6-DI-OSULFO-2-(SULFOAMINO)- ALPHA-D-GLUCOPYRANOSYL-(1-4)-O-2-O -SULFO-ALPHA-L-IDOPYRANURONOSYL-( 1-4)-2-DEOXY-2-(SULFOAMINO)-,6-(HYDR OGEN SULFATE), DECASODIUM SALT SR90107A ORG31540 GSK576428A	114870-03-0	0.5
Other components below reportable levels			99.5

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: impaired blood coagulation; bleeding.
<b>Indication of immediate medical attention and special treatment needed</b>	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 information centre.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Foam. Dry chemical powder. Carbon dioxide (CO2). Water.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	This product is expected to be non-combustible.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up**

Stop the flow of material, if this is without risk. Dike far ahead of spill for later disposal. Following product recovery, flush area with water.

**Environmental precautions**

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

**7. Handling and storage**

**Precautions for safe handling**

Avoid prolonged exposure. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection**

**Occupational exposure limits**

**GSK**

**Components**

**Type**

**Value**

FONDAPARINUX SODIUM  
(CAS 114870-03-0)

8 HR TWA

50 mcg/m3

OHC

3

**Biological limit values**

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

**Appropriate engineering controls**

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

Not normally needed.

**Hand protection**

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

**Other**

Not normally needed.

**Respiratory protection**

No personal respiratory protective equipment normally required.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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.

**9. Physical and chemical properties**

**Appearance**

**Physical state**

Liquid.

**Form**

Pre-filled syringe.

**Color**

Not available.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**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.

Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Percent volatile	98.7 % estimated

## 10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics	None known. The following adverse effects have been noted with therapeutic use of this material: impaired blood coagulation; bleeding.
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### Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test Results
FONDAPARINUX SODIUM (CAS 114870-03-0)		
Acute Other LD	Rat	> 40 mg/kg subcutaneous injection

\* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
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#### Irritation Corrosion - Skin

FONDAPARINUX SODIUM

Acute dermal irritation  
Result: Negative  
Species: Rabbit

Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
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#### Eye

FONDAPARINUX SODIUM

Acute ocular irritation  
Result: Negative  
Species: Rabbit

### Respiratory or skin sensitization

Respiratory sensitization	Not available.
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Skin sensitization	Health injuries are not known or expected under normal use.
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Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Health injuries are not known or expected under normal use.
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**Mutagenicity**

FONDAPARINUX SODIUM

Ames Assay, GLP assay  
 Result: Negative  
 Chromosomal Aberration Assay In Vitro, human lymphocytes  
 Result: Negative  
 Micronucleus Test, GLP assay  
 Result: Negative  
 Species: Rat  
 Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay  
 Result: Negative  
 Unscheduled DNA Synthesis in vivo  
 Result: Negative  
 Species: Rat

**Carcinogenicity** Health injuries are not known or expected under normal use. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** Health injuries are not known or expected under normal use.

**Reproductivity**

FONDAPARINUX SODIUM

Embryo-foetal development, sub-cutaneous administration  
 Result: NOAEL = 10 mg/kg/day (maximum dose); no adverse foetal effects  
 Species: Rabbit  
 Embryo-foetal development, sub-cutaneous administration  
 Result: NOAEL = 10 mg/kg/day (maximum dose); no adverse foetal effects  
 Species: Rat  
 Fertility, sub-cutaneous administration  
 Result: NOAEL = 10 mg/kg/day (maximum dose tested)  
 Species: Rat

**Specific target organ toxicity - single exposure** None known.

**Specific target organ toxicity - repeated exposure** None known.

**Aspiration hazard** Not likely, due to the form of the product.

**12. Ecological information**

**Ecotoxicity** The 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
FONDAPARINUX SODIUM (CAS 114870-03-0)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Algae > 100 mg/l, 96 hours QSAR Estimate
Crustacea	EC50	Daphnia > 100 mg/l, 48 hours QSAR Estimate
Fish	EC50	Fish > 100 mg/l, 96 hours QSAR Estimate

**Persistence and degradability** No data is available on the degradability of this product.

**Hydrolysis****Half-life (Hydrolysis-neutral)**

FONDAPARINUX SODIUM

&gt; 1 Years Measured, pH 7 Buffer Solution

**Bioaccumulative potential** No data available.

**Partition coefficient n-octanol / water (log Kow)**

FONDAPARINUX SODIUM

3.02 (Measured).

**Mobility in soil** No data available.

**Mobility in general** Not available.

**Volatility****Henry's law**

FONDAPARINUX SODIUM

> 9.67 atm m<sup>3</sup>/mol Calculated

**Other adverse effects** Not available.

**13. Disposal considerations**

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## 15. Regulatory information

**US federal regulations** One or more components are not listed on TSCA.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**  
 Immediate Hazard - Yes  
 Delayed Hazard - No  
 Fire Hazard - No  
 Pressure Hazard - No  
 Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations**

**US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**US. Rhode Island RTK**

Not regulated.

## US. California Proposition 65

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.

### 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, including date of preparation or last revision

<b>Issue date</b>	05-09-2014
<b>Revision date</b>	05-09-2014
<b>Version #</b>	06
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Regulatory Information: United States GHS: Classification