



FONDAPARINUX SODIUM (ARIXTRA) INJECTION SAFETY DATA SHEET

NORTH AMERICA GHS

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Fondaparinux Sodium (Arixtra) Injection

Synonyms: Arixtra (Fondaparinux Sodium Injection, USP) 2.5 mg/0.5 ml; Arixtra (Fondaparinux Sodium Injection, USP) 5 mg/0.4 ml; Arixtra (Fondaparinux Sodium Injection, USP) 7.5 mg/0.6 ml; Arixtra (Fondaparinux Sodium Injection, USP) 10 mg/0.8 ml

Intended Use of the Product

Use of the substance/mixture: Pharmaceutical. Subcutaneous. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:

Mylan N.V.
Building 4, Trident Place
Mosquito Way
Hatfield,
Hertfordshire
AL10 9UL, United Kingdom
+44 (0)1707 853000

www.mylan.com

Contact e-mail:

SDScontact@Mylan.com

Emergency Telephone Number

Emergency number

: For Hazardous Materials Incident
Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC (24 Hours)
Worldwide +1 703-741-5970

For reporting adverse health events, call:
+1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

Label Elements

GHS-US labeling: No labeling applicable

Other Hazards

Not available

Unknown acute toxicity (GHS-US)

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Fondaparinux Sodium	(CAS No) 114870-03-0	0.5 – 1.25	Acute Tox. 4 (Inhalation:dust,mist), H332

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: Please refer to the package insert for more detailed information.

Inhalation: None expected under normal conditions of use.

Skin Contact: May cause mild skin irritation.

Eye Contact: May cause eye irritation.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Injection: Common side effects include: pale skin, troubled breathing, unusual bleeding or bruising, unusual tiredness or weakness.

Chronic symptoms: Not available

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES**Extinguishing Media**

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None known.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not flammable.

Explosion hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: Use water spray or fog for cooling exposed containers.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Nitrogen compounds. Carbon oxides (CO, CO₂). Sodium oxides. Sulfur compounds.

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all contact with skin, eyes, or clothing.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Emergency procedures: Ventilate area. Stop release.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE**Precautions for Safe Handling**

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.

Control Parameters

Not available

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and vapors or mists may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical state	: Liquid
Appearance	: Clear, colorless to slightly yellow liquid
Odor and Odor threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper and Lower flammable limits	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density/Specific gravity	: Not available
Solubility	: Not available
Log Pow/Kow	: Not available
Viscosity	: Not available
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility of Hazardous Reactions Hazardous polymerization will not occur.

Conditions to Avoid Direct sunlight. Extremely high or low temperatures.

Incompatible Materials Strong oxidizers. Strong bases. Strong acids.

Hazardous Decomposition Products Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified

LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Aspiration Hazard: Not classified
Information on Toxicological Effects - Ingredient(s)
LD50 and LC50 Data: Not available

12. ECOLOGICAL INFORMATION

Toxicity

Not available

Persistence and Degradability

Not available

Bioaccumulative Potential

Not available

13. DISPOSAL CONSIDERATIONS

Sewage disposal recommendations: Do not dispose of waste into sewer.

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with ICAO/IATA/DOT/TDG

Not regulated for transportation as hazardous material or dangerous goods.

15. REGULATORY INFORMATION

US Federal Regulations

Not applicable

US State Regulations

Not applicable

Canadian Regulations

Fondaparinux Sodium (Arixtra) Injection

Uncontrolled product according to WHMIS classification criteria

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

16. OTHER INFORMATION

Revision date : 8 November 2016
Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
H332	Harmful if inhaled

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department

Phone Number: 304-599-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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