

Fondaparinux Sodium Injection USP

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Fondaparinux Sodium Injection USP 2.5 mg per 0.5 mL (NDC 55150-230); 5 mg per 0.4 mL (NDC 55150-231); 7.5 mg per 0.6 mL (NDC 55150-232); 10 mg per 0.8 mL (NDC 55150-233).

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
279 Princeton-Hightstown Rd.
E. Windsor, NJ 08520
T 888-238-7880

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. Label elements

GHS-US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Fondaparinux sodium	(CAS No) 114870-03-0	0.1 - 2	Not classified

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : 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.

First-aid measures after skin contact : Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

First-aid measures after eye contact : Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

First-aid measures after ingestion : 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.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : None anticipated under normal product handling conditions.

Symptoms/injuries after skin contact : May cause skin irritation.

Symptoms/injuries after eye contact : May cause eye irritation.

Symptoms/injuries after ingestion : May be harmful if swallowed.

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4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry chemical powder. Carbon dioxide (CO₂). Water.
Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged exposure.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Fondaparinux sodium (114870-03-0)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Wear chemical resistant gloves to minimize skin contact.
Eye protection : None required during normal product handling.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : None required during normal product handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Color : No data available
Odor : No data available
Odor threshold : No data available
pH : No data available
Melting point : No data available

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Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Contact with incompatible materials.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity – single exposure	: Not classified
Specific target organ toxicity – repeated exposure	: Not classified
Aspiration hazard	: Not classified

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SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. US State regulations

No additional information available

SECTION 16: Other information

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product