



SAFETY DATA SHEET

Revision date: 26-Aug-2016

Version: 3.1

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

Product Identifier

Material Name: Dalteparin Sodium Injection (Single-dose syringe)

Trade Name: Fragmin; Fragmine; Ligofragmin

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anticoagulant agent

Details of the Supplier of the Safety Data Sheet

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Pfizer Pharmaceuticals Group
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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|------------|------------|-----------------------|--------------------|---|
|------------|------------|-----------------------|--------------------|---|

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3. COMPOSITION / INFORMATION ON INGREDIENTS

| | | | | |
|------------------------------------|-----------|------------|------------|------|
| Dalteparin Sodium (Heparin Sodium) | 9041-08-1 | Not Listed | Not Listed | 5-12 |
|------------------------------------|-----------|------------|------------|------|

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|-----------------|------------|-----------------------|--------------------|---|
| Sodium chloride | 7647-14-5 | 231-598-3 | Not Listed | * |
| Water | 7732-18-5 | 231-791-2 | Not Listed | * |

Dalteparin Sodium (Heparin Sodium)

Registration Number: 01-2119430937-32-0000

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions: None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium chloride

Latvia OEL - TWA 5 mg/m³

Lithuania OEL - TWA 5 mg/m³

Dalteparin Sodium (Heparin Sodium)

Pfizer OEL TWA-8 Hr: 200µg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---|--------------------|--------------------------|-------------------------------|
| Physical State: | Solution | Color: | Colorless to pale straw-color |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
| Solvent Solubility: | No data available | | |
| Water Solubility: | No data available | | |
| Solubility: | Soluble: Water | | |
| pH: | 5.0-7.5 | | |
| Melting/Freezing Point (°C): | No data available | | |
| Boiling Point (°C): | No data available. | | |
| Partition Coefficient: (Method, pH, Endpoint, Value) | | | |
| Dalteparin Sodium (Heparin Sodium) | | | |
| No data available | | | |
| Water | | | |
| No data available | | | |
| Sodium chloride | | | |
| No data available | | | |
| Decomposition Temperature (°C): | No data available. | | |
| Evaporation Rate (Gram/s): | No data available | | |
| Vapor Pressure (kPa): | No data available | | |
| Vapor Density (g/ml): | No data available | | |
| Relative Density: | No data available | | |
| Specific Gravity: | 1.04 | | |
| Viscosity: | No data available | | |
| Flammability: | | | |
| Autoignition Temperature (Solid) (°C): | | No data available | |
| Flammability (Solids): | | No data available | |
| Flash Point (Liquid) (°C): | | No data available | |
| Upper Explosive Limits (Liquid) (% by Vol.): | | No data available | |
| Lower Explosive Limits (Liquid) (% by Vol.): | | No data available | |

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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10. STABILITY AND REACTIVITY

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

The information included in this section describes the potential hazards of the individual ingredients.

Short Term:

Mild eye irritant in experimental animals . May produce allergic reactions following skin contact.

Known Clinical Effects:

Clinical use of this drug has caused hemorrhage, gastrointestinal bleeding, increased bleeding time. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Dalteparin Sodium (Heparin Sodium)

Rat Oral LD 50 > 5000 mg/kg
Mouse Oral LD 50 > 5000mg/kg
Mouse Intraperitoneal LD 50 > 2500mg/kg
Rat Intraperitoneal LD 50 2500mg/kg
Mouse Intravenous LD 50 2800mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Dalteparin Sodium (Heparin Sodium)

Eye Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Dalteparin Sodium (Heparin Sodium)

Fertility and Embryonic Development Rat Subcutaneous 10 mg/kg/day NOAEL Fertility, Fetotoxicity
Embryo / Fetal Development Rat Intravenous 10,000 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Intravenous 2,500 mg/kg/day LOAEL Fetotoxicity

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

| | |
|---------------------------------------|---|
| Environmental Overview: | Environmental properties have not been investigated. Releases to the environment should be avoided. |
| Toxicity: | No data available |
| Persistence and Degradability: | No data available |
| Bio-accumulative Potential: | No data available |
| Mobility in Soil: | No data available |

13. DISPOSAL CONSIDERATIONS

| | |
|---------------------------------|---|
| Waste Treatment Methods: | Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. |
|---------------------------------|---|

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Sodium chloride

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 231-598-3 |

Water

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15. REGULATORY INFORMATION

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 231-791-2 |

Dalteparin Sodium (Heparin Sodium)

| | |
|--|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List | Not Listed |

16. OTHER INFORMATION

| | |
|------------------------------|--|
| Data Sources: | Pfizer proprietary drug development information. Publicly available toxicity information. |
| Reasons for Revision: | Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. |
| Revision date: | 26-Aug-2016 Product Stewardship Hazard Communication |
| Prepared by: | Pfizer Global Environment, Health, and Safety Operations |

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet