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

Product Identifier

<table>
<thead>
<tr>
<th>Material Name: Dalteparin Sodium Injection (Multiple-dose vial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name: Fragmin; Fragmine; Ligofragmin</td>
</tr>
<tr>
<td>Chemical Family: Mixture</td>
</tr>
</tbody>
</table>

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

Pfizer Inc

Pfizer Pharmaceuticals Group

235 East 42nd Street

New York, New York 10017

1-800-879-3477

Pfizer Ltd

Ramsgate Road

Sandwich, Kent

CT13 9NJ

United Kingdom

+00 44 (0)1304 616161

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

<table>
<thead>
<tr>
<th>Signal Word:</th>
<th>Not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements:</td>
<td>Not classified in accordance with international standards for workplace safety.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU/EINECS/EILINCS</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>

PZ03141
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Dalteparin Sodium (Heparin Sodium)</td>
<td>9041-08-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>5-12</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4 (H332)</td>
<td></td>
</tr>
</tbody>
</table>

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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

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 Aggravated by Exposure: None known  

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.

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

Benzyl Alcohol
Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 40 mg/m³
Finland OEL - TWA 10 ppm
 45 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
Poland OEL - TWA 240 mg/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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.)

**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

**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

**Benzy alcohol**

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
SAFETY DATA SHEET

Material Name: Dalteparin Sodium Injection (Multiple-dose vial)  
Revision date: 26-Aug-2016  
Version: 1.0

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

- **Sodium chloride**
  - Rat Oral LD50: 3000 mg/kg
  - Mouse Oral LD50: 4000 mg/kg

- **Benzyl Alcohol**
  - Rat Oral LD50: 1230 mg/kg
  - Rat Para-periosteal LD50: 53 mg/kg
  - Rat Inhalation LC50: >4.178 mg/L

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
11. TOXICOLOGICAL INFORMATION

Sodium chloride
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Benzy Alcohol
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Minimal
Skin Irritation  Guinea Pig  Moderate

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.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzy Alcohol
Pimephales promelas (Fathead Minnow)  EPA  LC50  96 Hours  460 mg/L
Daphnia magna (Water Flea)  OECD  EC50  48 Hours  230 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD  EC50  72 Hours  500 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzy Alcohol
Daphnia magna (Water Flea)  OECD  21 Day(s)  EC50  66 mg/L  Reproduction

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Benzy Alcohol
OECD  Activated sludge  Ready  92% After  14 Day(s)  Ready

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
- 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
15. REGULATORY INFORMATION

Benzyl Alcohol

- 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: 202-859-9

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Revision date: 26-Aug-2016

Prepared by: Product Stewardship Hazard Communication

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