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

Product Identifier

Material Name: HEPARIN SODIUM- heparin sodium injection
Trade Name: Heparin Sodium Injection, USP
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

Pfizer Inc
235 East 42nd Street
New York, NY 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
International Chemtrec (24 hours): +1-703-527-3887

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

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

<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>PZ03901</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
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>Dalteparin Sodium (Heparin Sodium)</td>
<td>9041-08-1</td>
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<td>Not Listed</td>
<td></td>
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<tr>
<td>SODIUM CHLORIDE</td>
<td>7647-14-5</td>
<td>231-598-3</td>
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</tr>
<tr>
<td>BENZYL ALCOHOL</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox. 4 (H302)</td>
<td>0.945</td>
</tr>
</tbody>
</table>

Water 7732-18-5 231-791-2 Not Listed *

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: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: This material produces toxic fumes of nitrogen and sulfur oxides, carbon dioxide, and carbon monoxide during fires.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting 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. Cleanup 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). Wash thoroughly after handling. 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 product used as anticoagulant agent

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Dalteparin Sodium (Heparin Sodium)**
- **Pfizer OEL TWA-8 Hr:** 200µg/m³

**SODIUM CHLORIDE**
- **Latvia OEL - TWA:** 5 mg/m³
- **Lithuania OEL - TWA:** 5 mg/m³

**BENZYL ALCOHOL**
- **Pfizer OEL TWA-8 Hr:** 10 ppm
- **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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/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.)

Skin:
Impervious disposable 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
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)

Water
No data available

BENZYL ALCOHOL
No data available

SODIUM CHLORIDE
No data available

Dalteparin Sodium (Heparin Sodium)
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
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: May cause eye irritation (based on components). 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)

**BENZYL ALCOHOL**
- **Rat** Oral LD 50 1230 mg/kg
- **Mouse** Oral LD 50 1360 mg/kg
- **Rabbit** Dermal LD 50 2 gm/kg

**SODIUM CHLORIDE**
- **Rat** Sub-tenon injection (eye) LC50/1hr > 42 g/m³
- **Rat** Oral LD 50 3 g/kg
- **Mouse** Oral LD 50 4 g/kg
- **Rabbit** Dermal LD 50 > 10 g/kg

**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

**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.
11. TOXICOLOGICAL INFORMATION

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

**SODIUM CHLORIDE**
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

**Dalteparin Sodium (Heparin Sodium)**
Eye Irritation  Rabbit  Mild

Reproduction & Developmental Toxicity: (Study Type, 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)

**BENZYL ALCOHOL**
Fathead Minnow  NPDES  LC-50  96 Hours  460 - 770 mg/L
Bluegill  NPDES  LC-50  96 Hours  10 mg/L
*Daphnia Magna* (Water Flea)  Surrogate  ErC50  48 Hours  23 - 400 mg/L

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Dalteparin Sodium (Heparin Sodium)</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Schedule 4</td>
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<td>Water</td>
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<td>Present</td>
<td>Present</td>
<td>231-791-2</td>
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<td>BENZYL ALCOHOL</td>
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<td>Present</td>
<td>Present</td>
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<td>202-859-9</td>
</tr>
</tbody>
</table>
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: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: New data sheet.

Revision date: 13-Jun-2019
Product Stewardship Hazard Communication


Pfizer Inc believes that the information contained in this 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