



# SAFETY DATA SHEET

Revision date 18-Jun-2025

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Heparin Sodium Injection, Sterile Solution, USP

**Product Code(s)** PZ01146

**Trade Name:** Heparin Sodium Injection, USP

**Item Code** H000401037, H000401038, H000401039, H000401040, H000401051, H000011691, H000401238

**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used as anticoagulant agent

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours): +1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

#### OSHA Classification

##### Hazards not otherwise classified (HNOC)

Not applicable

##### Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

### 2.2. Label elements

**Hazard statements** Not classified in accordance with international standards for workplace safety.

### 2.3. Other hazards

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

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

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

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Dalteparin Sodium (Heparin Sodium) (CAS #: 9041-08-1)	1,000-10,000 units/mL		Not Listed	Not classified	Not classified	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Dalteparin Sodium (Heparin Sodium) 9041-08-1	> 5000	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

### 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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

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## 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

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

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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## 4.3. Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	None.
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## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Dry chemical, CO2, alcohol-resistant foam or water spray.
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### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the chemical</b>	Not applicable.
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<b>Hazardous combustion products</b>	This material produces toxic fumes of nitrogen and sulfur oxides, carbon dioxide, and carbon monoxide during fires.
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#### **Explosion data**

<b>Sensitivity to mechanical impact</b>	No information available.
<b>Sensitivity to static discharge</b>	No information available.

### 5.3. Advice for firefighters

<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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## 6.3. Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
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## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

<b>Advice on safe handling</b>	Avoid breathing vapors or mists. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Store as directed by product packaging.
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### 7.3. Specific end use(s)

<b>Specific use(s)</b>	Pharmaceutical product used as. anticoagulant agent.
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## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

**Dalteparin Sodium (Heparin Sodium)**  
Pfizer OEL TWA-8 Hr: 200 µg/m<sup>3</sup>

### 8.2. Exposure controls

<b>Engineering controls</b>	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.
<b>Personal protective equipment</b>	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.

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<b>Eye/face protection</b>	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.).
<b>Hand protection</b>	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.).
<b>Skin and body protection</b>	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.).
<b>Respiratory protection</b>	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.).
<b>Thermal hazards</b>	No information available.
<b>Environmental exposure controls</b>	No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	Solution
<b>Physical state</b>	Liquid
<b>Color</b>	Colorless to pale straw-color
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b><u>Property</u></b>	<b><u>Values</u></b>
<b>Melting point / freezing point</b>	No data available
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
Lower explosion limit	No data available
Upper explosion limit	No data available
<b>Flash point</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
SADT (°C)	No data available
<b>pH</b>	5.0-7.5
pH (as aqueous solution)	No data available
<b>Kinematic viscosity</b>	No data available
Dynamic viscosity	No data available
<b>Solubility</b>	Soluble Water
<b>Vapor pressure</b>	No data available
<b>Density and/or relative density</b>	No data available
Bulk density	No data available
Liquid Density	No data available
<b>Vapor density</b>	No data available
<b>Particle characteristics</b>	
Particle Size	No information available
Particle Size Distribution	No information available

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## 9.2. Other information

**Molecular formula**

Mixture

**Molecular weight**

Mixture

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

**Reactivity**

No information available.

### 10.2. Chemical stability

**Stability**

Stable under normal conditions.

**Explosion data**

**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

### 10.4. Conditions to avoid

**Conditions to avoid**

Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

**Incompatible materials**

As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**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**

Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**

Based on available data, the classification criteria are not met.

**Skin corrosion/irritation**

Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization**

Based on available data, the classification criteria are not met.

**STOT - single exposure**

Based on available data, the classification criteria are not met.

**STOT - repeated exposure**

Based on available data, the classification criteria are not met.

**Reproductive toxicity**

Based on available data, the classification criteria are not met.

**Germ cell mutagenicity**

Based on available data, the classification criteria are not met.

**Carcinogenicity**

Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

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

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## 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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Dalteparin Sodium (Heparin Sodium)	> 779000 IU/kg ( Rat )	-	-

**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

## 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 NOEL Fertility, Fetotoxicity  
Embryo / Fetal Development Rat Intravenous 10,000 mg/kg/day LOEL Fetotoxicity  
Embryo / Fetal Development Rabbit Intravenous 2,500 mg/kg/day LOEL Fetotoxicity

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

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

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

### 12.1. Toxicity

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

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## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. Waste treatment methods

#### **Waste from residues/unused products**

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 wastewater 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.

## **Section 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.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable

## **Section 15: REGULATORY INFORMATION**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water



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**CERCLA/SARA Section 313 de minimus %**  
**California Proposition 65**  
**TSCA**  
**EINECS**  
**AICS**

Not Listed  
Not Listed  
Present  
231-791-2  
Present

Dalteparin Sodium (Heparin Sodium)

**CERCLA/SARA Section 313 de minimus %**  
**California Proposition 65**  
**TSCA**  
**EINECS**  
**AICS**

Not Listed  
Not Listed  
Present  
Not Listed  
Present

**Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)**

Schedule 4

## National regulations

### Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

TRGS 905

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material** Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable

**Major Accidents Ordinance SR 814.012** Not applicable

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### **Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### **Persistent Organic Pollutants**

Not applicable

#### **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

#### **Explosives Precursors Marketing and Use (2019/1148)**

Not applicable

#### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

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**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## **15.2. Chemical safety assessment**

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### **Key or legend to abbreviations and acronyms used in the safety data sheet**

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

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date** 18-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

**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.**