



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

Page 1 of 6

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Heparin Sodium Injection, Sterile Solution, USP

Trade Name: Heparin Sodium Injection, USP
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anticoagulant agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Benzyl Alcohol	100-51-6	202-859-9	*
Dalteparin Sodium (Heparin Sodium)	9041-08-1	Not listed	1,000-10,000 units/mL

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Water	7732-18-5	231-791-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to light yellow solution
Signal Word: WARNING

Statement of Hazard: May cause allergic reaction.
May cause adverse blood effects

Additional Hazard Information:

Short Term: Mild eye irritant in experimental animals .
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.

EU Indication of danger: Irritant

EU Hazard Symbols:



MATERIAL SAFETY DATA SHEET

Material Name: Heparin Sodium Injection, Sterile Solution,
USP

Revision date: 15-Dec-2006

Page 2 of 6

Version: 1.1

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

Eye Contact:	Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash skin with soap and water. Remove contaminated clothing. If irritation occurs or persists, get 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:	Generally none required. In accidental exposure to high levels, remove to fresh air. If discomfort occurs, get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	This material produces toxic fumes of nitrogen and sulfur oxides, carbon dioxide, and carbon monoxide during fires.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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

General Handling:	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
Storage Conditions:	Store as directed by product packaging.

MATERIAL SAFETY DATA SHEET

Material Name: Heparin Sodium Injection, Sterile Solution,
USP

Page 3 of 6

Revision date: 15-Dec-2006

Version: 1.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Dalteparin Sodium (Heparin Sodium)

Pfizer OEL TWA-8 Hr:

0.2mg/m³

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Rubber gloves

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Solution	Color:	Colorless to pale straw-color
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		
pH:	5.0-7.5		

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None

Incompatible Materials: None known

11. TOXICOLOGICAL INFORMATION

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

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	LD 50	4000 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Heparin Sodium Injection, Sterile Solution,
USP

Page 4 of 6

Revision date: 15-Dec-2006

Version: 1.1

Benzyl Alcohol

Rat Oral LD50 1.23 g/kg

Rat Intravenous LD50 53 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

Benzyl Alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

MATERIAL SAFETY DATA SHEET

Material Name: Heparin Sodium Injection, Sterile Solution,
USP

Page 5 of 6

Revision date: 15-Dec-2006

Version: 1.1

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic reaction.
May cause adverse blood effects

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B



Sodium chloride
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-598-3

Benzyl Alcohol
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 202-859-9

Water
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-791-2

Dalteparin Sodium (Heparin Sodium)
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
Standard for the Uniform Scheduling
for Drugs and Poisons: Schedule 4

MATERIAL SAFETY DATA SHEET

Material Name: Heparin Sodium Injection, Sterile Solution,
USP

Page 6 of 6

Revision date: 15-Dec-2006

Version: 1.1

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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.

End of Safety Data Sheet