SAFETY DATA SHEETS

This SDS packet was issued with item:

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#08
p. 1

Aventis

1. PRODUCT IDENTIFICATION

Trade Name: Lovenox

Aventis Pharmaceuticals, Inc.
Route 202-206
Bridgewater, NJ 08807-0800

Technical Information, M-F, 8 AM 5 PM EST: **(908) 231-4829**
24-Hour Transport Emergency, US (Chemtrec): **(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec) : **(703) 527-3887**
24-Hour Emergency, Aventis: **(908) 231-2666**

Synonyms:
Enoxaparin
Enoxaparin sodium

2. COMPOSITION / INFORMATION ON INGREDIENTS

	CAS#	CHEMICAL IDENTITY	EXPOSURE LIMITS					CARCINOGEN STATUS		
			ACGIH		OSHA		MANUF	IARC	NTP	OSHA
			TWA	STEL	STEL	PEL				
	9041-08-1	ENOXAPARIN SODIUM	NE	NE	NE	NE	20 ug/m3	NR	NR	NR
	7732-18-5	WATER	NE	NE	NE	NE	NE	NR	NR	NR

NE = Not Established NR = Not Reviewed * = OSHA Hazardous Ingredient

3. HAZARDS IDENTIFICATION

DMF I- 455576 C-00075062280
I- 454465 C-00075062300
DMF I- 454464 C-00075062160
DMF I- 416161 C-00175062603
I- 363024 C-00075062430
I- 483096 C- 00075062090
I- 512563 C- 00075291201

Emergency Overview No hazards expected.

Eye No data for determination of unusual hazard to the eyes are available at this time.

Skin Contact No adverse dermal effects are known.

Skin Absorption Not expected.

Ingestion Not intended for oral use but expected to be non-toxic by ingestion.

Inhalation Not an expected route of exposure.

Chronic Effects/ Carcinogenicity None known.

4. FIRST AID MEASURES

Eyes Flush with water for 15 minutes. If irritation develops, seek medical attention.

Skin Wash with soap and water. Seek medical attention if symptoms appear.

Ingestion Seek medical attention if symptoms appear.

Inhalation Seek medical attention if symptoms appear.

Note to Physician Accidental overdosage following administration of Lovenox Injection may lead to hemorrhagic complications. This may be largely neutralized by the slow intravenous injection of protamine sulfate (1% solution). The dose of protamine sulfate should be equal to the dose of Lovenox Injection injected: 1 mg protamine sulfate should be administered to neutralize 1 mg Lovenox Injection. A second infusion of 0.5 mg/mg protamine sulfate per 1 mg of Lovenox Injection may be administered if the APTT measured 2 to 4 hours after the first infusion remains prolonged. However, even with higher doses of protamine, the APTT may remain more prolonged than under normal conditions found following administration of conventional heparin. In all cases, the anti-Factor Xa activity is never completely neutralized (maximum about 60%). Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulfate, it should be given only when resuscitation techniques and treatment of anaphylactic shock are readily available. For additional information consult the labeling of Protamine Sulfate Injection, USP, products.

5. FIRE FIGHTING MEASURES

General Hazards Only potential fire hazard would involve packaging material.

Fire Fighting Extinguishing Media In case of fire use waterspray, foam or dry chemical. (S43)

Fire Fighting Instructions In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. (S43)

Hazardous Combustion Products Packaging material fires may produce carbon monoxide and other gaseous asphyxiants plus airborne particulate matter, soot and smoke.

6. ACCIDENTAL RELEASE MEASURES

Large Spill Contain spill. Absorb on suitable medium and deposit in container for disposal. Mop area.

Small Spill Absorb on paper towels. Deposit in suitable container for disposal. Broken glass requires additional caution.

7. HANDLING AND STORAGE

Special Handling Prevent physical damage to package.

Special Storage Lovenox Injection should be stored at or below 25 deg C. Do not freeze.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection Clean up, manufacturing and packaging operations may require safety glasses or goggles if there is a potential for splashing.

Skin Protection Latex gloves or gloves of equal or greater protection are recommended for spill clean-up, manufacturing and packaging operations.

Respiratory Protection None normally required.

Engineering Controls Clean-up, manufacturing and packaging operations should be required so as to offer no significant exposure to the ingredients.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pre-filled syringe.
Color:	Clear
Physical State:	Liquid
pH:	5.5 - 7.5
% Volatile:	90 % (water)

10. STABILITY AND REACTIVITY

Incompatibility No known incompatibilities.

Hazardous Decomposition Products No known hazardous decomposition products.

Hazardous Polymerization Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

General Information Lovenox Injection should be stored at or below 25 deg C. Do not freeze.

11. TOXICOLOGICAL INFORMATION

Toxicology Text The incidence of hemorrhagic complications during Lovenox Injection treatment has been low. During clinical trials with Lovenox Injection, moderate thrombocytopenia, defined as a platelet count between 100,000/mm^3 and 50,000/mm^3 occurred at a rate of 1.9% in patients given Lovenox, 2.0% in patients given heparin, and 1.7% in patients given placebo following hip or knee replacement surgery. Other adverse effects that were thought to be possibly or probably related to treatment with Lovenox Injection, heparin or placebo in clinical trials with patients undergoing hip or knee replacement surgery, and that occurred at a rate of at least 2% in the enoxaparin group, are fever, hemorrhage, nausea, hypochromic anemia, edema and peripheral edema.

A single subcutaneous dose of 46.4 mg/kg enoxaparin was lethal to rats. The symptoms of acute toxicity were ataxia, decreased motility, dyspnea, cyanosis and coma.

12. ECOLOGICAL INFORMATION

Ecological Information No information for determination of unusual environmental fate or toxicity is available at this time.

13. DISPOSAL CONSIDERATIONS

Disposal Information (S35) This material and its container must be disposed of in a safe way.

Waste Disposal Methods Waste must be disposed of in accordance with federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

DOT/IATA

Proper Shipping Name: Not Regulated

Transportation of Hazardous Material Description Not a regulated material. See current DOT or IATA shipping regulations.

15. REGULATORY INFORMATION

TSCA Inventory Status: This product is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

16. OTHER INFORMATION

MSDS No:	272
Prepared By:	David Eberts CIH
Approved By:	ITAC
Title:	Director Occupational Health and Industrial Tox
Approved Date:	01/24/03
Supersedes Date:	12/26/02

Other Information The information contained herein is based upon data considered true and accurate. Aventis Pharmaceuticals makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Revision Summary Second revision.

1. Product and Company Identification

PRODUCT NAME: LOVENOX® (enoxaparin sodium injection)
30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL,
100 mg/1 mL, 120 mg/0.8 mL, 150 mg/1 mL

Substance name: Enoxaparin sodium

Supplier:
Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec):	**(703) 527-3887**
US Customer Service	**(800) 207-8049**
24-Hour Emergency, sanofi-aventis US:	**(908) 981-5550**

Product use: Pharmaceutical product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification: not classified as a hazardous substance or mixture.

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, enoxaparin sodium:

Signal Word: None required.

Hazard Statement(s): None required.

Symbol(s): None required.

Precautionary Statement(s):

- Prevention: None required.
- Response: None required.
- Storage: None required.
- Disposal: None required.

2.3 Hazards Not Otherwise Classified (HNOC)

None known.

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3. Composition/Information on Ingredients

Chemical Name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
Enoxaparin sodium	Enoxaparin sodium	679809-58-6	100 mg/mL or 150 mg/mL

Non-hazardous ingredients: Water for injection.

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4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with product, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause slight eye and/or skin irritation.

Most common adverse reactions (>1%) from clinical use were bleeding, anemia, thrombocytopenia, elevation of serum aminotransferase, diarrhea, and nausea.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

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6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

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7. Handling and Storage

7.1 Precautions for Safe Handling

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Keep container tightly closed. Protect from light. Store in a cool, well-ventilated area.
Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F).

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8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, enoxaparin sodium: 0.02 mg/m^3, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

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9. Physical and Chemical Properties

Appearance: clear, colorless to pale yellow aqueous solution.
Odor: no data available.
Odor threshold: no data available.
pH: 5.5 to 7.5
Melting point/ Freezing point: no data available.
Initial boiling point/boiling point range: no data available.
Flash point: no data available.
Evaporation rate: no data available.
Flammability: no data available.
Upper/lower flammability or explosive limits: no data available.
Vapor pressure: no data available.
Vapor density: no data available.
Relative density: no data available.
Solubility (enoxaparin sodium): 50 g/l. Soluble in water.
Partition coefficient, n-octanol/water (enoxaparin sodium): Log (Kow): -1.2. Method: OECD 107.
Auto-ignition temperature: no data available.
Decomposition temperature: no data available.
Viscosity: no data available.

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10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

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11. Toxicological Information

The following information is for the active ingredient enoxaparin sodium unless otherwise noted:

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Most common adverse reactions were bleeding, diarrhea, and nausea.

Effects of short-term (acute) exposure: Anemia, thrombocytopenia, elevation of serum aminotransferase.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD_{50}): Oral route, rat: > 5,000 mg/kg.

Skin corrosion/irritation: Slight irritant. Species: rabbit.

Serious eye damage/irritation: Slight irritant. Species: rabbit.

Sensitization: Rare cases of cutaneous allergic reactions.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: No long-term studies in animals have been performed to evaluate the carcinogenic potential of enoxaparin.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Teratology studies have been conducted in pregnant rats and rabbits at SC doses of enoxaparin up to 30 mg/kg/day corresponding to 211 mg/m^2/day and 410 mg/m^2/day in rats and rabbits respectively. There was no evidence of teratogenic effects or fetotoxicity due to enoxaparin. Enoxaparin was found to have no effect on fertility or reproductive performance of male and female rats at SC doses up to 20 mg/kg/day or 141 mg/m^2/day.

Mutagenicity: Enoxaparin was not mutagenic in in vitro tests, including the Ames test, mouse lymphoma cell forward mutation test, and human lymphocyte chromosomal aberration test, and the in vivo rat bone marrow chromosomal aberration test.

Aspiration hazard: No data available.

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12. Ecological Information

The following information is for the active ingredient enoxaparin sodium unless otherwise noted:

12.1. Ecotoxicity

Toxicity on invertebrates: (EC50): > 100 mg/l
Species: Daphnia magna
Duration of exposure: 48 h
Method: Tested according to Directive 92/69/EEC.

Algae toxicity (EC50): > 100 mg/l
Species: Desmodesmus subspicatus
Duration of exposure: 72 h
Method: OECD 201

Algae toxicity (NOEC): ≥ 100 mg/l
Species: Scenedesmus subspicatus
Duration of exposure: 72 h
Method: OECD 201

12.2. Persistence and degradability

Biological degradability: 90 %
Duration of test: 28 d
Method: OECD 301A / ISO 7827
The product is readily biodegradable according to OECD criteria.

12.3. Bioaccumulative potential

Unlikely to be bioaccumulative in living organisms (Log Kow < 3).

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

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13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

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14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

15. Regulatory Information

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.
Massachusetts Right-To-Know List: Not listed.
New Jersey Right-To-Know List: Not listed.
Pennsylvania Right-To-Know List: Not listed.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms
CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

Date Prepared: November 16, 2016