



MATERIAL SAFETY DATA SHEET

Date of preparation: January 8, 2007

1. PRODUCT IDENTIFICATION

Product Name(s): LOVENOX

**sanofi-aventis U.S.
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: (816) 966-6300

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>CHEMICAL IDENTITY</u>	<u>CAS#</u>
Enoxaparin sodium	9041-08-1
Water for injection	7732-18-5

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.

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.

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

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/mm³ and 50,000/mm³ 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 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

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

Other Information The information contained herein is based upon data considered true and accurate. Sanofi-aventis 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.