1. Product and Company Identification

PRODUCT NAME: ENOXAPARIN SODIUM INJECTION, 300 mg/3 mL
Multiple Dose Vial

Supplier:
Winthrop U.S.
A business of Sanofi 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:	**(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.

---

3. Composition/Information on Ingredients

Chemical name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
Enoxaparin sodium	Enoxaparin sodium	679809-58-6	100 mg/mL (9.0%)
Benzyl alcohol	Benzyl alcohol (preservative)	100-51-6	15 mg/mL (1.3%)
Water	Water for injection	7732-18-5	Balance (> 89%)

---

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.

---

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.

---

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.

---

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).

---

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

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

Benzyl alcohol, AIHA WEEL: 10 ppm 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.

---

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
Partition coefficient, n-octanol/water (benzyl alcohol): Log (Kow): 1.10 (experimental)
Auto-ignition temperature: no data available.
Decomposition temperature: no data available.
Viscosity: no data available.

---

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.

---

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. May cause slight eye and/or skin irritation.

Effects of short-term (acute) exposure: Anemia, thrombocytopenia, elevation of serum aminotransferase. May cause slight eye and/or skin irritation.

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

Acute toxicity (LD_{50}):
Enoxaparin sodium: Oral route, rat: > 5,000 mg/kg.
Benzyl alcohol: Oral route, rat: 1,230 mg/kg
Benzyl alcohol: Inhalation route, rat: > 0.5 mg/l

Skin corrosion/irritation:
Enoxaparin sodium: Slight irritant. Species: rabbit
Benzyl alcohol: non-irritant.

Serious eye damage/irritation:
Enoxaparin sodium: Slight irritant. Species: rabbit.
Benzyl alcohol: Moderate 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.

Enoxaparin sodium and benzyl alcohol are not listed by NTP, and are not found to be potential carcinogens 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.

Benzyl alcohol: No evidence of teratogenicity in several rodent studies.

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.

Benzyl alcohol was negative in the Ames test with and without metabolic activation.

Aspiration hazard: No data available.

---

12. Ecological Information

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

12.1. Ecotoxicity

Enoxaparin sodium:

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

Benzyl alcohol:

Fish toxicity (LC50): 10 mg/l
Species: Lepomis macrochirus
Exposure duration: 96 h

Toxicity on invertebrates: 400 mg/l
Species: Daphnia magna
Exposure duration: 24 h

Algae toxicity (IC5): 640 mg/l
Species: Scenedesmus quadricauda
Exposure duration: 96 h

12.2. Persistence and degradability

Enoxaparin sodium:

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

Benzyl alcohol:

Biological degradability: 92 - 96 %
Testing period: 28 d
The product is readily biodegradable according to OECD criteria.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

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.

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: Benzyl alcohol is listed.
New Jersey Right-To-Know List: Benzyl alcohol is listed.
Pennsylvania Right-To-Know List: Benzyl alcohol is listed.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Winthrop U.S. 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
AIHA: American Industrial Hygiene Association
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
WEEL: Workplace environmental exposure level

Date Prepared: February 13, 2017
Third version.