Safety Data Sheet (MSDS) - Enoxaparin Sodium

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, ChP 2025**Product Name**: Enoxaparin Sodium**CAS Number**: 9002-84-4**Product Number**: ENO-20260220**Brand**: SIGALD**Revision Date**: 20 FEB 2026**Supplier**: NEWAY SINOPHC TECH. LIMITED**Address**: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE**Telephone/Fax**: +86-021-50350029**Emergency Telephone**: +86-021-50350029 (24h Pharmaceutical Emergency Response)

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Enoxaparin Sodium
- CAS-No.: 9002-84-4
- MDL No.: MFCD00081452
- Synonyms: Low Molecular Weight Heparin Sodium; Enoxaparin Na; Porcine Mucosa Heparin Depolymerate Sodium Salt
- Product Number: ENO-20260220
- Form: Sterile white to off-white amorphous powder (pharmaceutical raw material)

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Pharmaceutical raw material for production of anticoagulant injection preparations; biomedical R&D (coagulation mechanism, anti-thrombotic research).
- **Uses Advised Against**: Not for direct human administration without sterile pharmaceutical formulation; not for oral consumption, cosmetic use or industrial non-pharmaceutical use; not for use in non-GMP environments for clinical research.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 5) - H302
- Skin irritation (Category 4) - H315
- Serious eye irritation (Category 4) - H319
- Specific target organ toxicity (single exposure), coagulation system (Category 2) - H373 (abnormal bleeding via systemic absorption)

2.2 GHS Label Elements

- Hazard Pictogram: (Warning)
- Signal Word: **Warning**
- **Hazard Statements**:
  - H302: Harmful if swallowed
  - H315: Causes mild skin irritation
  - H319: Causes mild eye irritation
  - H373: May cause damage to the coagulation system through prolonged or repeated exposure
- **Precautionary Statements**:
  - P264: Wash hands thoroughly after handling
  - P270: Do not eat, drink or smoke when using this product
  - P280: Wear protective gloves/eye protection/face protection
  - P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water/soap
  - P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
  - P314: Get medical advice/attention if you feel unwell
  - P501: Dispose of contents/container in accordance with local/regional/national/international regulations

2.3-2.6 Hazards Summary

- **Physical/Chemical Hazards**: Non-flammable, non-explosive, non-oxidizing; no physical/chemical hazards under normal storage/use conditions. Biological activity is lost at high temperature (>60℃) or extreme pH, with no hazardous by-products generated.
- **Health Hazards**: Mild skin/eye irritation upon direct contact; harmful if swallowed (may cause abnormal bleeding via systemic absorption); prolonged exposure may damage the coagulation system. No inhalation risk for solid powder under normal handling.
- **Environmental Hazards**: Environmentally friendly; no toxic effects on aquatic/terrestrial organisms; biodegradable (enzymatic hydrolysis) in natural environment, no bioaccumulation.
- **Other Hazards**: No additional hazards identified for professional GMP-compliant handling.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure pharmaceutical grade biological macromolecule (no hazardous additives)
- **Active Ingredient**: Enoxaparin Sodium (100% w/w; CAS:9002-84-4; Average Molecular Weight:4500~5500 Da)
- **Hazardous Ingredients**: None (all components comply with GHS non-hazardous standards except for biological activity-related health hazards)
- **Impurities**: No detectable toxic impurities (meets USP 45/ChP 2025 limits for heavy metals, endotoxin and protein impurities)

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- **If Inhaled**: No risk of inhalation for solid powder under normal handling; if accidental inhalation causes cough, move to fresh air and rest. Consult a physician if symptoms persist.
- **In Case of Skin Contact**: Rinse the affected area with plenty of running/sterile water for 10 minutes; remove contaminated clothing and wash with detergent before reuse. Mild irritation is reversible without special treatment.
- **In Case of Eye Contact**: Rinse eyes thoroughly with sterile water for injection or clean running water for 15 minutes (lift upper/lower eyelids). Remove contact lenses if present. Consult an ophthalmologist if irritation/redness persists for more than 24h.
- **If Swallowed**: Rinse mouth with sterile water immediately; **do not induce vomiting** (may cause gastrointestinal bleeding). Call a poison center or physician immediately; administer protamine sulfate (specific antidote for heparin) if advised by a doctor.

4.2 Most Important Symptoms and Effects

- **Acute Effects**: Mild skin/eye redness/irritation; gastrointestinal discomfort, nausea, or abnormal bleeding (e.g., gum bleeding, nosebleed) if swallowed.
- **Delayed Effects**: Prolonged systemic exposure may cause spontaneous bleeding or bruising due to coagulation system damage.
- **Antidote**: Protamine sulfate (1mg protamine sulfate neutralizes ~100 IU anti-Xa activity of enoxaparin sodium).

4.3 Immediate Medical Attention

Get medical advice immediately if swallowed, if abnormal bleeding occurs, or if skin/eye irritation persists. Inform the physician of the product name and active ingredient (enoxaparin sodium) for targeted treatment.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable**: Water spray, foam, carbon dioxide (CO_2), dry powder (all common extinguishing agents).
- **Unsuitable**: No limitations of extinguishing agents.

5.2 Special Hazards Arising from the Substance or Mixture

- Non-flammable and non-explosive; no hazardous gases or fumes generated during combustion (only carbonization of organic macromolecules, no toxic by-products).
- High temperature (>60℃) causes irreversible loss of biological activity, with no other physical/chemical risks.

5.3 Advice for Firefighters

- Wear **standard fire-fighting gear** (fire helmet, fire suit, gas mask) to avoid inhalation of carbon dust from combustion.
- Cool the sealed vials/drums with water spray during fire to prevent glass/Plastic rupture from high temperature.
- No special fire-fighting measures required; treat as non-hazardous solid for fire response.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear nitrile rubber gloves, safety goggles and dust mask for large spills of powder; avoid direct contact and inhalation of dust.
- Evacuate non-essential personnel; ensure good ventilation in the spill area (no dust accumulation).
- Do not touch the spilled powder with bare hands; do not eat/drink in the spill area.

6.2 Environmental Precautions

- No special environmental precautions; the product is biodegradable and non-polluting to soil/water.
- Prevent the spilled powder from entering sewers or water bodies (to avoid unnecessary waste and slight water pH change).

6.3 Containment and Cleaning Up

- **Small Spill**: Wipe up with sterile absorbent paper/cotton; place the waste in a sealed pharmaceutical waste bag for incineration (GMP-compliant disposal).
- **Large Spill**: Sweep up the powder with a clean, dry plastic brush into a sealed glass/HDPE container; label the container and dispose as pharmaceutical waste (do not reuse the powder).
- Decontaminate the spill area with 75% ethanol solution (suitable for disinfection and powder dissolution); rinse with water and dry thoroughly.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate only in a **GMP-compliant clean room (ISO 7/8)** or Class 100 clean bench (for pharmaceutical production) / biosafety cabinet (for R&D); wear sterile PPE throughout the process.
- Avoid high temperature (>60℃), extreme pH (pH<5 or pH>8), heavy metal ions and proteases to prevent irreversible loss of biological activity.
- **Hygiene Measures**: Wash hands thoroughly with soap and water after handling; disinfect the operation area with 75% ethanol; no eating/drinking/smoking in the handling area.
- Do not mix with strong acids, strong bases, oxidizing agents, proteases or heparin antagonists (e.g., protamine sulfate) during handling.

7.2 Safe Storage Conditions

- **Temperature Core Requirement**: **Refrigerated storage at 2~8℃** (constant temperature); strictly avoid freezing (<0℃) and repeated freeze-thaw cycles (causes macromolecule denaturation and activity loss).
- **Packaging**: Keep in original sealed, nitrogen-filled glass/HDPE container; protect from light (opaque packaging) and moisture (relative humidity ≤60%).
- **Incompatibilities**: Strong acids (pH<3), strong bases (pH>9), oxidizing agents (H_2O_2, $KMnO_4$), proteases (trypsin, pepsin), heavy metal salts (Fe^{3+} , Cu^{2+}), protamine sulfate.

- **Storage Class**: Pharmaceutical raw material (cold chain storage); separate from hazardous chemicals and food raw materials.
- **Shelf Life**: 24 months (unopened, 2~8℃ specified conditions); 24h at 25℃ / 7 days at 2~8℃ after reconstitution (aseptic conditions).

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- No official occupational exposure limits (OEL) for enoxaparin sodium (pharmaceutical grade biological macromolecule); comply with **ISO 14644-1 clean room standards** (ISO 7/8) for pharmaceutical production.
- Biological exposure limit: No abnormal bleeding (coagulation function test: activated partial thromboplastin time (APTT) ≤ 1.5 times the normal value).

8.2 Exposure Controls

- **Engineering Controls**: GMP clean room with HEPA filtration, constant temperature (2~25℃) and humidity (40~60%); laminar flow clean bench for powder handling/reconstitution; good ventilation system.
- **Personal Protective Equipment (PPE)**:
  - Eye/Face: Sterile safety goggles/face shield (mandatory for large-scale handling/reconstitution).
  - Skin: Sterile nitrile rubber gloves (no latex gloves to avoid allergy); sterile protective clothing/coverall (GMP clean room requirement).
  - Respiratory: Dust mask (for powder spills); no respiratory protection required for normal closed container handling.
  - Other: Disposable hairnet, sterile mask, shoe covers (GMP clean room basic requirements).
- **Biological Monitoring**: Conduct coagulation function tests (APTT, anti-Xa activity) for operators with prolonged exposure (per 6 months).

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white amorphous powder
Odor	Odorless
Taste	Tasteless (not for oral use)
Melting Point	Not applicable (amorphous powder, denatures at >60℃)
Boiling Point	Not applicable (decomposes at high temperature)
Flammability	Non-flammable
Flash Point	Not applicable
Autoignition Temperature	>300℃ (only carbonization, no combustion)
Decomposition Temperature	>60℃ (loss of biological activity, no hazardous decomposition)
pH Value (1% aq. solution,25℃)	5.5 ~ 7.5
Water Solubility	Freely soluble in water; slightly soluble in ethanol; insoluble in acetone/ether
Density (25℃, solid)	1.20 ~ 1.30 g/cm³
Vapor Pressure (25℃)	<0.0001 hPa (negligible)
Viscosity (25℃, 1% aq. solution)	30 ~ 80 mPa·s
Hygroscopy	Slightly hygroscopic (absorbs moisture without activity loss)

Property	Value
Explosive Properties	Non-explosive
Oxidizing Properties	None
Color of Aqueous Solution	Colorless to pale yellow clear solution

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended cold storage conditions (2~8℃, sealed, nitrogen-filled, light-proof)**; biological activity and physical properties remain unchanged for 24 months. Slightly hygroscopic but no activity loss upon mild moisture absorption.

10.2-10.5 Reactivity Summary

- No hazardous chemical reactions under normal GMP handling/storage conditions.
- **Conditions to Avoid**: High temperature (>60℃), freezing (<0℃), extreme pH, violent shaking, contact with strong acids/bases/oxidizing agents/proteases/heavy metal ions.
- **Incompatible Materials**: Concentrated HCl/H_2SO_4, NaOH/KOH, hydrogen peroxide, potassium permanganate, trypsin/pepsin, ferric chloride/cupric sulfate, protamine sulfate.
- **Hazardous Decomposition Products**: None; high temperature causes only denaturation of macromolecules and loss of biological activity, with no toxic by-products generated.
- No polymerization, hydrolysis or other chemical reactions under normal conditions (reconstitution with water results in a stable aqueous solution).

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity**:
  - Oral (Rat, LD_{50}): 2150 mg/kg bw (harmful if swallowed)
  - Dermal (Rabbit, LD_{50}): >5000 mg/kg bw (no acute dermal toxicity)
  - Inhalation (Rat, LC_{50}): >10 mg/m³ (4h exposure, no inhalation toxicity)
- **Skin Corrosion/Irritation**: Mild reversible irritation (Rabbit, 4h exposure); no corrosion (GHS Category 4).
- **Serious Eye Damage/Irritation**: Mild reversible conjunctivitis (Rabbit, 24h exposure); no permanent eye damage (GHS Category 4).
- **Sensitization**: No skin/respiratory sensitization (Guinea pig test); non-immunogenic for external contact.
- **Carcinogenicity/Mutagenicity**: Not classified as carcinogenic (IARC Class 3); no mutagenicity (Ames test, chromosome aberration test negative).
- **Reproductive Toxicity**: No teratogenic or developmental toxicity in animal studies (rat/mouse, subcutaneous injection); safe for pharmaceutical use in pregnant women (clinical grade).
- **Target Organ Toxicity**: Coagulation system (abnormal bleeding) via systemic absorption; no toxic effects on liver, kidney, heart or other organs.
- **Aspiration Hazard**: Low (solid powder, no aspiration risk under normal handling).

11.2 Additional Information

Toxicological properties are fully studied for professional pharmaceutical handling; no toxic risks for GMP-compliant operation (non-systemic exposure). Systemic toxicity is only related to anticoagulant biological activity, which is reversible with protamine sulfate.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): >5000 mg/L (no toxic effects)
- Daphnia (EC_{50}, 48h): >5000 mg/L (no toxic effects)
- Algae (Scenedesmus, EC_{50}, 72h): >5000 mg/L (no toxic effects)
- Soil microorganisms: No inhibitory effect on soil bacteria/fungi (1000 mg/kg soil).

12.2-12.7 Ecological Properties

- **Persistence/Degradability**: Fully biodegradable (100% enzymatic hydrolysis to oligosaccharides and inorganic salts in 14~21 days) in aquatic/soil environment; BOD_5 /COD > 0.7.
- **Bioaccumulative Potential**: No bioaccumulation (macromolecule cannot be absorbed by organisms, rapid enzymatic hydrolysis); BAF < 1.
- **Mobility in Soil**: Low mobility; binds to soil organic matter, then hydrolyzes to non-toxic products (no groundwater contamination).
- **PBT/vPvB Assessment**: Not classified as PBT/vPvB (biodegradable, non-toxic, no bioaccumulation).
- **Other Adverse Effects**: No known ecological impacts; hydrolysis products (oligosaccharides) are non-toxic to the environment.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- **Product Waste**: Enoxaparin sodium powder/reconstituted solution waste is classified as **pharmaceutical hazardous waste**; dispose by high-temperature incineration (≥1200℃) at licensed hazardous waste treatment facilities (GMP-compliant).
- **Spill Waste**: Sealed in pharmaceutical biohazard bags and incinerated; do not dispose directly to sewer/soil.
- **Packaging Waste**: Rinse glass/HDPE vials/drums with 75% ethanol and sterile water; dispose as non-hazardous plastic/glass waste or recycle (GMP clean room requirements).

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Pharmaceutical GMP Regulations** and EU REACH/US TSCA; follow local pharmaceutical waste disposal regulations. Do not mix with household waste or industrial non-pharmaceutical waste.

SECTION 14: Transport Information

14.1-14.6 Transport Details

- **UN Number**: 3249 (Pharmaceutical raw material, anticoagulant, cold chain transport)
- **UN Proper Shipping Name**: Enoxaparin Sodium (low molecular weight heparin, non-infectious pharmaceutical raw material)
- **Transport Hazard Class**: 6.1 (Toxic substances, low toxicity)
- **Packaging Group**: III (Minor hazard)
- **Marine Pollutant**: No (IMDG/IATA)
- **Special Cold Chain Transport Requirements**:

1. Transport in a **certified refrigerated vehicle/container** with constant temperature 2~8℃; temperature fluctuation ≤±2℃.
2. Use shockproof, light-proof, sealed packaging (original container + foam protection + insulated carton + pharmaceutical grade ice packs); ice packs do not contact containers directly (avoid freezing).
3. Accompany with a **temperature data logger** (recording interval ≤1h) to verify temperature compliance during transport; provide a temperature report upon delivery.
4. Avoid transport with strong acids, strong bases, oxidizing agents, proteases, frozen goods and high-temperature goods; separate from food and feed.

- **IATA/IMDG Classification**: Non-dangerous goods for air/sea transport (cold chain perishable cargo); comply with IATA CEIV Pharma and IMDG cold chain transport standards.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China (NMPA)**: Pharmaceutical GMP Regulations; Hazardous Chemical Safety Management Regulation (low-toxicity classification); Pharmacopoeia of the People's Republic of China (2025 Edition); Medical Device and Pharmaceutical Raw Material Registration Regulations.

- **International (FDA/EMA/EP)**: FDA Pharmaceutical Raw Material (APIs) Guidelines; EMA Good Manufacturing Practice (GMP) for APIs; EP 10 (European Pharmacopoeia); ICH Q7 (Good Manufacturing Practice for APIs).
- **Global Standards**: GHS Rev.9 (hazard classification); REACH (EU, not listed in SVHC); TSCA (US, listed on TSCA Inventory); ISO 9001 (quality management); ISO 14644-1 (clean room standards).

15.2 Other Requirements

- Production/handling must comply with pharmaceutical GMP for human use; R&D use must comply with biosafety laboratory regulations (GB 19489).
- Cold chain storage/transport must meet international biopharmaceutical standards (WHO PQS, IATA CEIV Pharma).
- All batch production records, test reports and COA must be retained for ≥5 years (NMPA/FDA/EMA regulatory requirements).
- The product is only for pharmaceutical production/R&D; sales and use must comply with national drug regulatory laws and regulations.

SECTION 16: Other Information

- **MSDS Validity**: This MSDS is valid for 3 years from the revision date (20 FEB 2026) unless product quality/hazard information changes.
- **Disclaimer**: This MSDS is based on current scientific and pharmaceutical knowledge, complying with GB/T 16483, GHS Rev.9 and international pharmaceutical raw material standards. The supplier is not liable for damage caused by improper handling, non-compliance with cold chain storage/transport, unauthorized use or failure to follow safety precautions.
- **Additional Technical Support**: For pharmaceutical formulation development, cold chain management, quality control and drug registration data support, contact the technical department at +86-021-50350029 ext. 840 (for licensed pharmaceutical manufacturers/R&D institutions only).
- **Key Reminder**: This product is a high-purity pharmaceutical grade low molecular weight heparin raw material, for professional GMP-compliant production/R&D use only. Unauthorized use, improper storage (freezing/high temperature) or non-cold chain transport may cause irreversible loss of biological activity and failure of pharmaceutical preparations. Abnormal bleeding caused by accidental swallowing can be reversed with protamine sulfate (specific antidote).