



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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HEPARIN SODIUM SYSTEM SUITABILITY

Catalog Number: 1304049

Revision Date:

May 2, 2008

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Heparin Sodium System Suitability

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Irritant.

Adverse Effects: Adverse effects following heparin injection may include pale skin; troubled breathing; unusual bleeding or bruising; unusual tiredness or weakness; dizziness; headache; paralysis; red or dark brown urine; red or black, tarry stools; swelling of the ankles, feet, or fingers; pain or numbness in extremities; blue or purple patches in skin; irritability; lightheadedness; confusion; convulsions; fever; organ tissue death; and stroke. There are reports of lowered blood pressure, facial swelling, rapid heartbeat, hives, and nausea in patients who received heparin contaminated with oversulfated chondroitin sulfate. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects following injection may include bleeding complications.

Acute: Eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, bleeding or blood disorders, ulceration, liver or kidney function impairment, hypertension, enoxaparin or heparin-induced thrombocytopenia, recent surgery or childbirth, endocarditis, severe trauma, and prosthetic heart valves.

Cross Sensitivity: Persons sensitive to pork or pork products may be sensitive to this material also.

Target Organs: Blood

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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Common Name: Heparin Sodium System Suitability

Formula: n/f

Synonym: n/f

Chemical Name: n/f

CAS: See Composition

RTECS Number: See Composition

Chemical Family: Mucopolysaccharide

Therapeutic Category: Antithrombic

Composition: Heparin Sodium (CAS # 9041-08-1, RTECS # MI0850000) : < 90%
Oversulfated chondroitin sulfate : > 10%

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. Heparin is not absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey

involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: 0.02 mg/m³ (Enoxapin sodium)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: Fine white powder.

Odor Threshold: n/f

pH: 6.8

Melting Range: n/f

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: n/f

Fat Solubility: n/f

Other Solubility: n/f

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: n/f

Molecular Weight: n/f

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SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits toxic fumes. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 4850 mg/kg (Heparin sodium)

Oral Mouse: LD50: >5000 mg/kg (Heparin sodium)

Other Toxicity Data: n/f

Irritancy Data: Rabbit/skin, eye: slight (Enoxaparin sodium)

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: n/f

Mutagenicity Data: Enoxaparin (a low molecular weight heparin) was not mutagenic in vitro in the Ames test, the mouse lymphoma cell forward mutation test, or the human lymphocyte chromosomal aberration test. It was not mutagenic in vivo in the rat bone marrow chromosomal aberration test. Enoxaparin did not cause a disruption of chromosomes in vitro in rat bone marrow cells or in vivo in human peripheral lymphocytes.

Reproductive and Developmental Effects: Enoxaparin (a low molecular weight heparin) can cause an increased risk of bleeding or hemorrhage in pregnant women.
There was no evidence of birth defects in rats and rabbits administered enoxaparin at doses up to 30 mg/kg/day and 410 mg/m2/day, respectively. There was no effect on fertility or reproductive performance in male and female rats administered subcutaneous doses of enoxaparin at 2400 and 4800 IU/kg/day, respectively.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: n/f

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SECTION 16 - OTHER INFORMATION

Revision: 02-May-08**Previous Revision Date:** None