1. Identification

Product identifier: Enoxaparin Sodium Molecular Weight Calibrant B

Other means of identification:

Catalog number: 1235864

Chemical name: Heparin, sodium salt

Synonym(s): Ardeparin sodium, heparin sodium, dalteparin sodium

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:

Company name: U. S. Pharmacopeia

Address: 12601 Twinbrook Parkway

Rockville

MD

20852-1790

United States

Telephone: RS Technical Services, 301-816-8129

Website: www.usp.org

E-mail: RSTECH@usp.org

Emergency phone number:

CHEMTREC within US & Canada: 1-800-424-9300

CHEMTREC outside US & Canada: +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Serious eye damage/eye irritation Category 2B

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Hazard symbol: None.

Signal word: Warning

Hazard statement: Causes eye irritation.

Precautionary statement:

Prevention: Wash thoroughly after handling.

Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Storage: Not available.

Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): Not classified.

Other hazards which do not result in classification: None known.

3. Composition/information on ingredients

Mixture

Non-hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enoxaparin Molecular Weight 2870</td>
<td>Ardeparin sodium, heparin sodium, dalteparin sodium</td>
<td>679809-58-6</td>
<td>33.34</td>
</tr>
</tbody>
</table>
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Irritant effects.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe 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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enoxaparin Sodium Molecular Weight Calibrant B</td>
<td>TWA</td>
<td>20 micrograms/m3</td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment

**Eye/face protection**
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Hand protection**

**Other**

**Respiratory protection**

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

**Appearance**
Fine white to almost white powder.

**Physical state**
Solid.

**Form**
Powder.

**Odor**
Almost odorless.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
Not available.

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not applicable.

**Upper/lower flammability or explosive limits**
Flammability limit - lower (%)
Not available.

**Flammability limit - upper (%)**
Not available.

**Explosive limit - lower (%)**
Not available.

**Explosive limit - upper (%)**
Not available.

**Vapor pressure**
Not available.

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility in water**
Freely soluble.

**Partition coefficient (n-octanol/water)**
-1.2

**Auto-ignition temperature**
Not available.

**Decomposition temperature**
Not available.
Viscosity
Not available.

Other information
Chemical family
Polysaccharide.

pH in aqueous solution
6.2 - 7.7 (10% solution)

Solubility (other)
Practically insoluble in ethanol, in acetone, and in chloroform.

10. Stability and reactivity

Reactivity
Not available.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
NOx, SOx, Na2O. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion
Based on available data, the classification criteria are not met.

Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Causes eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

Cross sensitivity
Persons sensitive to beef or pork may be sensitive to this material also.

Medical conditions aggravated by exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enoxaparin Sodium Molecular Weight Calibrant B Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Mouse</td>
<td>&gt; 5000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LD50 Rat</td>
<td>&gt; 5000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>4850 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Due to lack of data the classification is not possible.

Serious eye damage/eye irritation
Causes eye irritation.

Local effects

| Enoxaparin Sodium Molecular Weight Calibrant B | Irritancy test |
|                                              | Result: Irritant. |
|                                              | Species: Rabbit |
|                                              | Organ: Eye |
|                                              | Severity: Mild |

Respiratory or skin sensitization

Respiratory sensitization
Based on available data, the classification criteria are not met. Rare occurrences of anaphylactic reactions following therapeutic use of this material have been reported.

Skin sensitization
Based on available data, the classification criteria are not met. Rare occurrences of dermal hypersensitivity reactions with therapeutic use of this material have been reported.

Skin sensitization

| Enoxaparin Sodium Molecular Weight Calibrant B | Passive cutaneous anaphylaxis assay |
|                                              | Result: Non-sensitizing. |
|                                              | Species: Guinea pig |

Germ cell mutagenicity
Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.
Carcinogenicity
Due to lack of data the classification is not possible.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity
Based on available data, the classification criteria are not met.
Enoxaparin (a low molecular weight heparin) can cause an increased risk of bleeding or hemorrhage when used during pregnancy.
This material does not cross the placenta.

Reproductivity
Enoxaparin Sodium Molecular Weight Calibrant B
Reproductivity and development study, administered intravenously during gestation
Result: No maternal or fetal toxicity observed.
Species: Rat

Specific target organ toxicity - single exposure
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure
Based on available data, the classification criteria are not met.

Aspiration hazard
Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enoxaparin Sodium Molecular Weight Calibrant B</td>
<td>Acute Crustacea</td>
<td>EC50 Daphnia magna &gt; 100 mg/l, 48 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
Readily biodegradable.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

Waste from residues / unused products
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not available.

15. Regulatory information

US federal regulations
All components are on the U.S. EPA TSCA Inventory List.
CERCLA/SARA Hazardous Substances - Not applicable.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Hazard - Yes</td>
<td></td>
</tr>
<tr>
<td>Delayed Hazard - No</td>
<td></td>
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<tr>
<td>Fire Hazard - No</td>
<td></td>
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<tr>
<td>Pressure Hazard - No</td>
<td></td>
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<tr>
<td>Reactivity Hazard - No</td>
<td></td>
</tr>
</tbody>
</table>

SARA 302 Extremely hazardous substance
Not listed.
SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California Proposition 65
Not Listed.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 09-01-2011
Revision date 10-13-2015
Version # 03

Further information Not available.

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Revision Information
Hazard(s) identification: Prevention
Toxicological information: Delayed and immediate effects of exposure
GHS: Classification