



# SAFETY DATA SHEET

## 1. Identification

|                                                        |                                                                     |                 |
|--------------------------------------------------------|---------------------------------------------------------------------|-----------------|
| Product identifier                                     | Heparin Sodium System Suitability                                   |                 |
| Other means of identification                          |                                                                     |                 |
| Catalog number                                         | 1304049                                                             |                 |
| 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 |                                                                     |                 |
| Company name                                           | U. S. Pharmacopeia                                                  |                 |
| Address                                                | 12601 Twinbrook Parkway<br>Rockville<br>MD<br>20852-1790<br>US      |                 |
| 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 |
| OSHA hazard(s)                            | Not classified.                                                                                                                                                                            |             |
| Label elements                            |                                                                                                                                                                                            |             |
| Hazard symbol                             | No symbol.                                                                                                                                                                                 |             |
| 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.                                                                                                                                                                            |             |

## 3. Composition/information on ingredients

### Mixture

#### Hazardous components

| Chemical name  | Common name and synonyms | CAS number | %         |
|----------------|--------------------------|------------|-----------|
| Heparin Sodium |                          | 9041-08-1  | 80 - < 90 |

#### Non-hazardous components

| Chemical name                    | Common name and synonyms | CAS number | %         |
|----------------------------------|--------------------------|------------|-----------|
| Oversulfated Chondroitin Sulfate |                          |            | 10 - < 20 |

## 4. First-aid measures

|              |                                                                                                                                                                                |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inhalation   | Move to fresh air. Call a physician if symptoms develop or persist.                                                                                                            |
| Skin contact | Rinse with water. 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. If eye irritation persists: Get medical advice/attention. |

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ingestion</b>                                                              | Rinse mouth thoroughly. Get medical attention if symptoms occur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Most important symptoms/effects, acute and delayed</b>                     | Irritation of eyes and mucous membranes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Indication of immediate medical attention and special treatment needed</b> | Provide general supportive measures and treat symptomatically. Slow infusion of protamine sulfate 1% solution will neutralize heparin sodium. However, protamine sulfate can cause hypotensive and anaphylactoid reactions, and should only be administered when resuscitation techniques and treatment of anaphylactoid shock are available. (PDR)                                                                                                                                                                                    |
| <b>General information</b>                                                    | 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

|                                                                      |                                                                                                                                           |
|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Suitable extinguishing media</b>                                  | Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.                                     |
| <b>Unsuitable extinguishing media</b>                                | None known.                                                                                                                               |
| <b>Specific hazards arising from the chemical</b>                    | No unusual fire or explosion hazards noted.                                                                                               |
| <b>Special protective equipment and precautions for firefighters</b> | Wear suitable protective equipment.                                                                                                       |
| <b>Fire-fighting equipment/instructions</b>                          | As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| <b>Specific methods</b>                                              | Cool containers exposed to flames with water until well after the fire is out.                                                            |

## 6. Accidental release measures

|                                                                            |                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal precautions, protective equipment and emergency procedures</b> | Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment. |
| <b>Methods and materials for containment and cleaning up</b>               | 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. Wash spill site.                                                                         |

## 7. Handling and storage

|                                                                     |                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Precautions for safe handling</b>                                | 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. |
| <b>Conditions for safe storage, including any incompatibilities</b> | 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

#### Industrial Use

| Components                     | Type | Value             |
|--------------------------------|------|-------------------|
| Heparin Sodium (CAS 9041-08-1) | TWA  | 200 micrograms/m3 |

### 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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

### Individual protection measures, such as personal protective equipment

#### Eyeface 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.

|                                       |                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Skin protection</b>                |                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Hand protection</b>                | 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. |
| <b>Other</b>                          | For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.                                                                                                                                                                                                 |
| <b>Respiratory protection</b>         | 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).                                                                                                                                                         |
| <b>Thermal hazards</b>                | Not available.                                                                                                                                                                                                                                                                                                                                                                             |
| <b>General hygiene considerations</b> | Handle in accordance with good industrial hygiene and safety practice.                                                                                                                                                                                                                                                                                                                     |

## 9. Physical and chemical properties

|                                                |                    |
|------------------------------------------------|--------------------|
| <b>Appearance</b>                              | Fine white powder. |
| <b>Physical state</b>                          | Solid.             |
| <b>Form</b>                                    | Powder.            |
| <b>Odor</b>                                    | Not available.     |
| <b>Odor threshold</b>                          | Not available.     |
| <b>Melting point/freezing point</b>            | Not available.     |
| <b>Initial boiling point and boiling range</b> | Not available.     |
| <b>Flash point</b>                             | Not available.     |
| <b>Evaporation rate</b>                        | Not available.     |
| <b>Flammability (solid, gas)</b>               | Not applicable.    |

### Upper/lower flammability or explosive limits

|                                                |                |
|------------------------------------------------|----------------|
| <b>Flammability limit - lower (%)</b>          | Not available. |
| <b>Flammability limit - upper (%)</b>          | Not available. |
| <b>Explosive limit - lower (%)</b>             | Not available. |
| <b>Explosive limit - upper (%)</b>             | Not available. |
| <b>Vapor pressure</b>                          | Not available. |
| <b>Vapor density</b>                           | Not available. |
| <b>Relative density</b>                        | Not available. |
| <b>Solubility in water</b>                     | Not available. |
| <b>Partition coefficient (n-octanol/water)</b> | Not available. |
| <b>Auto-ignition temperature</b>               | Not available. |
| <b>Decomposition temperature</b>               | Not available. |
| <b>Viscosity</b>                               | Not available. |

## 10. Stability and reactivity

|                                           |                                                                                                                                         |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reactivity</b>                         | No reactivity hazards known.                                                                                                            |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.                                                                                             |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                                                             |
| <b>Conditions to avoid</b>                | None known.                                                                                                                             |
| <b>Incompatible materials</b>             | Strong oxidizing agents.                                                                                                                |
| <b>Hazardous decomposition products</b>   | NO <sub>x</sub> , SO <sub>x</sub> , Na <sub>2</sub> O. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

## 11. Toxicological information

### Information on likely routes of exposure

|                     |                                                                   |
|---------------------|-------------------------------------------------------------------|
| <b>Ingestion</b>    | Based on available data, the classification criteria are not met. |
| <b>Inhalation</b>   | Due to lack of data the classification is not possible.           |
| <b>Skin contact</b> | Due to lack of data the classification is not possible.           |

|                                                                                      |                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye contact</b>                                                                   | Causes eye irritation.                                                                                                                                                                                                                                                                                                    |
| <b>Symptoms related to the physical, chemical, and toxicological characteristics</b> | There are reports of lowered blood pressure, facial swelling, rapid heartbeat, hives, and nausea in patients who received infusions of heparin contaminated with oversulfated chondroitin sulfate. Heparin (injection; infusion): Nosebleeds. Blood in urine. Tarry stools. Bruising. Increased bleeding time. Hair loss. |
| <b>Delayed and immediate effects of exposure</b>                                     | Heparin (injection; infusion): Thrombocytopenia. Kidney function impairment. Hypersensitivity.                                                                                                                                                                                                                            |
| <b>Cross sensitivity</b>                                                             | Persons sensitive to pork or pork products may be sensitive to this material also.                                                                                                                                                                                                                                        |
| <b>Medical conditions aggravated by exposure</b>                                     | Heparin (injection; infusion): Bleeding disorders such as thrombocytopenia and hemophilia. Active bleeding. Stomach ulcers. Kidney or liver impairment. Hypertension.                                                                                                                                                     |

#### Acute toxicity

| Components                     | Species | Test Results |
|--------------------------------|---------|--------------|
| Heparin Sodium (CAS 9041-08-1) |         |              |
| <b>Acute</b>                   |         |              |
| <i>Oral</i>                    |         |              |
|                                | Mouse   | > 5000 mg/kg |
|                                | Rat     | > 5000 mg/kg |

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

**Serious eye damage/eye irritation** Causes eye irritation.

#### Local effects

Heparin Sodium

Irritancy  
Result: Positive  
Species: Rabbit  
Organ: Eye  
Severity: Mild

**Respiratory sensitization** Due to lack of data the classification is not possible.

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

**Germ cell mutagenicity** Due to lack of data the classification is not possible.

**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.

#### Reproductivity

Heparin Sodium

10 mg/kg/day (subcutaneous), NOAEL - fertility, fetotoxicity  
Species: Rat  
10000 mg/kg/day (intravenous), LOAEL - fetotoxicity  
Species: Rat  
2500 mg/kg/day (intravenous), LOAEL - fetotoxicity  
Species: Rabbit

**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

|                                      |                                                            |
|--------------------------------------|------------------------------------------------------------|
| <b>Ecotoxicity</b>                   | No ecotoxicity data noted for the ingredient(s).           |
| <b>Persistence and degradability</b> | No data is available on the degradability of this product. |
| <b>Bioaccumulative potential</b>     | Not available.                                             |
| <b>Mobility in soil</b>              | Not available.                                             |
| <b>Other adverse effects</b>         | Not available.                                             |

## 13. Disposal considerations

**Disposal instructions** This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

**Local disposal regulations** Not available.

**Hazardous waste code** Not regulated.

**Waste from residues / unused products** 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).

|                               |                                                                                                                                                                                                            |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Contaminated packaging</b> | 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 a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

|                                                                                 |                           |
|---------------------------------------------------------------------------------|---------------------------|
| <b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b> | No information available. |
|---------------------------------------------------------------------------------|---------------------------|

## 15. Regulatory information

|                               |                                                    |
|-------------------------------|----------------------------------------------------|
| <b>US federal regulations</b> | CERCLA/SARA Hazardous Substances - Not applicable. |
|-------------------------------|----------------------------------------------------|

All components are on the U.S. EPA TSCA Inventory List.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

|                          |                                                                                                                    |
|--------------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>Hazard categories</b> | Immediate Hazard - No<br>Delayed Hazard - No<br>Fire Hazard - No<br>Pressure Hazard - No<br>Reactivity Hazard - No |
|--------------------------|--------------------------------------------------------------------------------------------------------------------|

|                                               |    |
|-----------------------------------------------|----|
| <b>SARA 302 Extremely hazardous substance</b> | No |
|-----------------------------------------------|----|

|                                        |    |
|----------------------------------------|----|
| <b>SARA 311/312 Hazardous chemical</b> | No |
|----------------------------------------|----|

### Other federal regulations

|                                       |                |
|---------------------------------------|----------------|
| <b>Safe Drinking Water Act (SDWA)</b> | Not regulated. |
|---------------------------------------|----------------|

|                                           |                |
|-------------------------------------------|----------------|
| <b>Food and Drug Administration (FDA)</b> | Not regulated. |
|-------------------------------------------|----------------|

|                             |                                                                                                                                                                                                |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>US state regulations</b> | 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. |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### International Inventories

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

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

|                            |                |
|----------------------------|----------------|
| <b>Issue date</b>          | 05-02-2008     |
| <b>Revision date</b>       | 01-07-2013     |
| <b>Version #</b>           | 02             |
| <b>Further information</b> | Not available. |

**Disclaimer**

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

**Revision Information**

This document has undergone significant changes and should be reviewed in its entirety.