SAFETY DATA SHEET

1. Identification

Product identifier Protamine Sulfate

Other means of identification
Catalog number 1578612
CAS number 9009-65-8
Chemical name Protamine sulfate

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 Sensitization, respiratory Category 1
Sensitization, skin Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapors/spray. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.

Response If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.
Supplemental information
None.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Protamine Sulfate</td>
<td></td>
<td>9009-65-8</td>
<td>100</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. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a poison center or doctor/physician.

**Skin contact**
Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

**Eye contact**
Rinse with water. 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**
Sensitization.

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

**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.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

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

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**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

**Occupational exposure limits**
No exposure limits noted for ingredient(s).

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**
For laboratory operations, use good technique and limit open handling. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

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

**Eye/face protection**
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection**

**Hand protection**
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Other**
Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**
Respirators are generally not required for laboratory operations. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**
Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

**Appearance**
Appearance descriptions are general information and not specific to any USP lot.

**Physical state**
Solid.

**Form**
Crystalline powder.

**Color**
White. Off-white.

**Odor**
Not available.

**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 available.

**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(ies)**

**Solubility (water)**
Slightly soluble.

**Solubility (other)**
Ethanol: Insoluble.
Ether: Insoluble.

**Auto-ignition temperature**
Not available.

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

10. Stability and reactivity
Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid Contact with incompatible materials.
Incompatible materials Strong oxidizing agents.
Hazardous decomposition products NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact May cause an allergic skin reaction.
Eye contact Knowledge about health hazard is incomplete.
Ingestion Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical and toxicological characteristics

Information on toxicological effects
Acute toxicity Not known.
Skin corrosion/irritation Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation Knowledge about health hazard is incomplete.
Respiratory or skin sensitization
Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization May cause an allergic skin reaction.
Germ cell mutagenicity Knowledge about mutagenicity is incomplete.
Mutagenicity
E. coli assay Result: Negative.
S. typhimurium Ames assay Result: Negative.
Carcinogenicity Knowledge about carcinogenicity is incomplete.
IARC Monographs. Overall Evaluation of Carcinogenicity Not listed.
US. National Toxicology Program (NTP) Report on Carcinogens Not listed.
Reproductive toxicity Knowledge about health hazard is incomplete.
Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.
Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information
Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability No data is available on the degradability of this substance.
Bioaccumulative potential No data available.
Mobility in soil No data available.
Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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).

Contaminated packaging

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 applicable.

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Respiratory or skin sensitization

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.
US state regulations

California Proposition 65
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. For more information go to www.P65Warnings.ca.gov.

International Inventories

<table>
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<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
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<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
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<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<td>New Zealand</td>
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<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
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*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) and 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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>Revision date</th>
<th>Version #</th>
<th>Disclaimer</th>
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<td>10-30-2013</td>
<td>08-28-2020</td>
<td>02</td>
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