1. Identification

Product identifier: Pentamidine Isethionate

Other means of identification:
- Catalog number: 1504900
- Chemical name: 4,4’-Diamidinodiphenoxypentane isethionate
- Synonym(s): Diamidine; Pentamidine Isetionate

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, Rockville, MD 20852-1790, 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:
- Acute toxicity, oral: Category 4
- Skin corrosion/irritation: Category 2
- Serious eye damage/eye irritation: Category 2A
- Sensitization, skin: Category 1
- Specific target organ toxicity, single exposure: Category 3 respiratory tract irritation

OSHA hazard(s): Not classified.

Label elements

Signal word: Warning

Hazard statement: Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction. May cause respiratory irritation.

Precautionary statement

Prevention: Wash thoroughly after handling. Wear protective gloves. Contaminated work clothing must not be allowed out of the workplace. Wear eye/face protection. Use only outdoors or in a well-ventilated area.

Response: If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. 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. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.

Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.

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

Hazard(s) not otherwise classified (HNOC): Not classified.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentamidine Isethionate</td>
<td></td>
<td></td>
<td>Diamidine; Pentamidine Isetionate</td>
<td>140-64-7</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. 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 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**
May cause allergic skin reaction. 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

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

**Exposure guidelines**
No exposure standards allocated.
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

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

Hand 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.

Other

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.

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**

White or almost white crystalline powder.

**Physical state**

Solid.

**Form**

Powder.

**Odor**

Slight odor.

**Odor threshold**

Not available.

**pH**

4.5 - 6.5 (5% aqueous solution)

**Melting point/freezing point**

Approximately 180 °C

**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**

< 0.0000001 kPa at 25 °C

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility in water**

Freely soluble.

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

Not available.

**Auto-ignition temperature**

Not available.

**Decomposition temperature**

Not available.

**Viscosity**

Not available.

**Other information**

**Chemical family**

Aromatic diamidine derivative, related to hydroxystilbamidine.

**Molecular formula**

C19H24N4O2 . 2C2H6O4S

**Molecular weight**

592.68
Solubility (other) Soluble in glycerol; slightly soluble in alcohol; insoluble in ether, in acetone, in chloroform, and in liquid petroleum.

10. Stability and reactivity
Reactivity No reactivity hazards known.
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 bases. 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
- Ingestion Harmful if swallowed.
- Inhalation May cause irritation to the respiratory system.
- Skin contact May cause an allergic skin reaction.
- Eye contact Causes serious eye irritation.
Acute toxicity Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentamidine Isethionate (CAS 140-64-7)</td>
<td>Mouse</td>
<td>600 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation Causes skin irritation.
Serious eye damage/eye irritation Causes serious eye irritation.
Respiratory sensitization Due to lack of data the classification is not possible.
Skin sensitization May cause an allergic skin reaction.
Germ cell mutagenicity Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity
- S. typhimurium Ames assay
  Result: Negative (with or without activation).
Carcinogenicity Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure Respiratory tract irritation.
Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.
Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information
Ecotoxicity No ecotoxicity data noted for the ingredient(s).
Persistence and degradability No data is available on the degradability of this product.
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 available.

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 a hazardous material by DOT.

IATA: Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: No information available.

15. Regulatory information

US federal regulations: CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories:
- Immediate Hazard - Yes
- Delayed Hazard - No
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

SARA 302 Extremely hazardous substance: No

SARA 311/312 Hazardous chemical: No

Other federal regulations:
- 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.

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>No</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>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</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>No</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>No</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>04-25-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>05-06-2014</td>
</tr>
<tr>
<td>Version #</td>
<td>02</td>
</tr>
<tr>
<td>Further information</td>
<td>Not available.</td>
</tr>
<tr>
<td>Disclaimer</td>
<td>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.</td>
</tr>
</tbody>
</table>

Revision Information

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