1. Identification

Product identifier: Mafenide Acetate

Other means of identification:
- Catalog number: 1373008
- Chemical name: Benzenesulfonamide, 4-(aminomethyl)-, monoacetate

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:
- Serious eye damage/eye irritation: Category 2B
- Sensitization, respiratory: Category 1B
- Sensitization, skin: Category 1B

OSHA hazard(s): Not classified.

Label elements

- Signal word: Danger
- Hazard statement: May cause an allergic skin reaction. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention: Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

Response: If on skin: Wash with plenty of water/soap. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Wash contaminated clothing before reuse.

Storage: Not available.

Disposal: Dispose of contents/container to an approved disposal site.

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

3. Composition/information on ingredients

Substance

Material name: Mafenide Acetate
4. First-aid measures

**Inhalation**
Move to fresh air. Call a physician if symptoms develop or persist. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

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

**Eye contact**
Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth thoroughly. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed**
Irritation of eyes and mucous membranes. May cause allergic skin reaction. May cause allergic respiratory reaction.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically. For allergic reactions, administer antihistamines. Continue fluid therapy. Administer sodium bicarbonate parenterally. (USP DI)

**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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

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. Wash spill site.

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>Mafenide Acetate (CAS 13009-99-9)</td>
<td>TWA</td>
<td>0.5 mg/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.

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 powderaed 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).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Slight acidic odor.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

323.6 - 341.6 °F (162 - 172 °C) ; also reported 151 - 152 °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

0.0000032 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
  Methylated sulfonamide.

- Molecular formula
  C7H10N2O2S.C2H4O2

- Molecular weight
  246.29
10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Stable at normal conditions.

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

Conditions to avoid
None under normal conditions.

Incompatible materials
Strong bases. Oxidizers.

Hazardous decomposition products
SOx. NOx. 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
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact
May cause an allergic skin reaction.

Eye contact
Causes eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics


Cross sensitivity
Persons sensitive to sulfonamides, furosemide, thiazide diuretics, sulfonylureas, or carbonic anhydrase inhibitors may be sensitive to this material also.

Acute toxicity
Due to lack of data the classification is not possible.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mafenide Acetate (CAS 13009-99-9)</td>
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<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Guinea pig</td>
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<tr>
<td></td>
<td>Mouse</td>
<td>10183 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>9212 mg/kg</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
Irritation test, at 40% concentration.
Result: Irritant.
Organ: Eye.
Severity: Mild.

Respiratory sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization
May cause an allergic skin reaction.

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
1 - 1000 mg/kg/day Reproductivity test
Result: Frequency of malformations was no greater than expected.
Species: Rat
1 g/kg Reproductivity test
Result: Some decrease in implantation but no congenital defects were noted.
Species: Mouse
600 mg/kg/day Reproductivity test
Result: No fetal toxicity.
Species: Rat

Specific target organ toxicity - single exposure
Due to lack of data the classification is not possible.

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: 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).
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 - No, 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: 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.

International Inventories

<table>
<thead>
<tr>
<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>
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<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
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<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<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>Country(s) or region</td>
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<td>-----------------------------</td>
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<td>Korea</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)*

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

<table>
<thead>
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<th>Issue date</th>
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<tr>
<td>Revision date</td>
<td>12-11-2012</td>
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<tr>
<td>Version #</td>
<td>02</td>
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<td>Further information</td>
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Revision Information

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