SAFETY DATA SHEET

1. Identification

Product identifier Mesalamine

Other means of identification

<table>
<thead>
<tr>
<th>Catalog number</th>
<th>1392705</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Benzoic acid, 5-amino-2-hydroxy-</td>
</tr>
<tr>
<td>Synonym(s)</td>
<td>5-Aminosalicylic acid</td>
</tr>
</tbody>
</table>

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

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.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Common name and synonyms</td>
</tr>
<tr>
<td>Mesalamine</td>
<td>5-Aminosalicylic acid</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.
Irritation of eyes and mucous membranes.

Treatment of salicylate overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. Multiple doses may be beneficial. Perform gastric lavage, unless contraindicated, soon after ingestion. Protect airway and control seizures first. Correct dehydration with sodium chloride until good urine flow is obtained. Do not over hydrate. Add potassium to subsequent fluid. Monitor pulmonary status, urine output, urine pH, and serum potassium. Alkalize urine with sodium bicarbonate to achieve a urine pH greater than 7.5. Additional potassium chloride may be required. For acidosis, administer sodium bicarbonate intravenously. Monitor ABGs. Treat hyperthermia with external cooling. Early treatment with hemodialysis may be useful if blood salicylate levels are high or if symptoms of salicylism persist. Hemodialysis rapidly increases salicylate clearance and corrects acid-base, fluid, and electrolyte disturbances. For seizures, administer a benzodiazepine intravenously. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte imbalances, and hypoxia. For active bleeding or coagulation disorders, give blood or blood platelets if needed. Vitamin K may improve prothrombin time. [Poisindex]

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.

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.

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.

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.

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.
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).

Thermal hazards
Not available.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
White, tan, or pink crystalline powder.

Physical state
Solid.

Form
Powder.

Odor
Odorless.

Odor threshold
Not available.

pH
3.5 - 4.5 (2.5% suspension in water)

Melting point/freezing point
500 - 536 °F (260 - 280 °C) (decomposes)

Initial boiling point and boiling range
Not available.

Flash point
536.00 °F (280.00 °C)

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
Slightly soluble.

Partition coefficient (n-octanol/water)
-0.16

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Chemical family
Aminosalicylate.

Molecular formula
C7H7NO3

Molecular weight
153.14

Solubility (other)
Soluble in dilute hydrochloric acid and in dilute alkali hydroxides; very slightly soluble in dehydrated alcohol, in acetone, and in methyl alcohol; practically insoluble in n-butyl alcohol, in chloroform, in ether, and in ethyl acetate.

Specific gravity
1

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.
Hazardous decomposition products | 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:** 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 olsalazine, sulfasalazine, or salicylates may be sensitive to this material also.

**Medical conditions aggravated by exposure**


**Acute toxicity**

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesalamine (CAS 89-57-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rat</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>2800 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**

- Irritancy test: Irritant.
  - Species: Rabbit
  - Organ: Skin
  - Severity: Mild

**Respiratory sensitization**

Due to lack of data the classification is not possible.

**Skin sensitization**

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

**Sensitization**

- Sensitization test: Non-sensitizing.
  - Species: Guinea pig
  - Organ: Skin

**Germ cell mutagenicity**

Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

**Mutagenicity**

- Chromosomal aberrations in Chinese hamster ovary cells: Negative.
- Forward and reverse E. coli mutation assays: Negative.
- Mouse micronucleus test: Negative.
- S. typhimurium Ames assay: Negative.

**Carcinogenicity**

Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

< 2000 mg/kg Carcinogenicity study
- Result: Not carcinogenic in dietary study.
- Species: Mouse
< 480 mg/kg Carcinogenicity study
Result: Not carcinogenic in dietary study.
Species: Rat

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

Reproductivity
< 320 mg/kg/day Reproductivity study
Result: Did not impair fertility or harm the fetus.
Species: Rat
< 495 mg/kg/day Reproductivity study
Result: Did not impair fertility or harm the fetus.
Species: Rabbit

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

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
Safe Drinking Water Act (SDWA)
Not regulated.
Food and Drug Administration (FDA)

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>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>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>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</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</td>
<td>Yes</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)*

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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>09-22-2009</th>
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<tbody>
<tr>
<td>Revision date</td>
<td>10-30-2014</td>
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<tr>
<td>Version #</td>
<td>02</td>
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<tr>
<td>Further information</td>
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Revision Information

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