SAFETY DATA SHEET

1. Identification

Product identifier Silver Sulfadiazine

Other means of identification

Catalog number 1612608
Chemical name Benzenesulfonamide, 4-amino-N-2-pyrimidinyl-, monosilver (1+) salt
Synonym(s) Sulfadiazine, Silver

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

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

Physical hazards Not classified.

Health hazards

Sensitization, respiratory Category 1
Sensitization, skin Category 1

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

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

Precautionary statement

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

Response 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. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Storage Not available.

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

Substance

Material name: Silver Sulfadiazine
7226  Version #: 02  Revision date: 08-21-2014  Issue date: 10-04-2007
4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

**Skin contact**
Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.

**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. May cause allergic respiratory reaction.

**Indication of immediate medical attention and special treatment needed**
Treatment of sulfonamide overdose should be symptomatic and supportive and may include the following: 1. Administer activated charcoal as a slurry. 2. For hypotension, infuse with 10 to 20 mL/kg isotonic fluid, place in Trendelenburg position. If hypotension persists, administer dopamine or norepinephrine. 3. If kidney function is normal, consider diuresis to obtain a urine flow of 3 to 6 mL/kg/hr. 4. For anuria or agranulocytosis, dialysis and/or isolation should be considered. Obtain a baseline CBC, hepatic and renal function test. 5. For seizures, administer a benzodiazepine. Consider phenobarbital if seizures recur. 6. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. [Meditext]

**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

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silver Sulfadiazine (CAS 22199-08-2)</td>
<td>PEL</td>
<td>0.01 mg/m³</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Material</th>
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</thead>
<tbody>
<tr>
<td>Silver Sulfadiazine (CAS 22199-08-2)</td>
<td>REL</td>
<td>0.01 mg/m³</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silver Sulfadiazine (CAS 22199-08-2)</td>
<td>TWA</td>
<td>0.01 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 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 or creamy white crystalline powder.

Physical state
Solid.

Form
Powder.

Odor
Slight odor.

Odor threshold
Not available.

pH
5.5 - 7

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 Slightly 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 sulfanilamide derivative (sulfonamide).
Molecular formula C10H9AgN4O2S
Molecular weight 357.14
Solubility (other) Practically insoluble in alcohol, in chloroform, and in ether; slightly soluble in acetone; freely soluble in 30% ammonia solution.

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 known.
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

<table>
<thead>
<tr>
<th>Route</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical, and toxicological characteristics


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


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>Silver Sulfadiazine (CAS 22199-08-2)</td>
<td>Oral</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>&gt; 10000 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Due to lack of data the classification is not possible.
Local effects
1 - 20 % Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin
Test Duration: 13 weeks
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.
Data from germ cell mutagenicity tests were not found.
Sulfadiazine has been associated with chromosomal aberrations in lymphocytes of exposed pharmaceutical workers and in vitro tests.

Mutagenicity
Based on available data, the classification criteria are not met.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Studies in rats have shown that long-term administration of sulfonamides may cause thyroid malignancy. However, rats appear to be especially susceptible to the goitrogenic effects of sulfonamides.

Carcinogenicity
Due to lack of data the classification is not possible.

Reproductive toxicity
Due to lack of data the classification is not possible.
Sulfonamides given to pregnant women prior to delivery may cause jaundice, brain damage, and hemolytic anemia in the offspring. Studies in rats and mice given high oral doses have shown that certain sulfonamides cause a significant increase in the incidence of cleft palate and other bony abnormalities in the fetus. A review of limited human pregnancy data has not demonstrated an increase in developmental effects. Related material: Silver was toxic in vitro to washed human sperm. It is not known if this material causes the same effects.

Reproductivity
11 g/kg Reproductivity study
Result: Decreased litter size occurred after subcutaneous injection of females prior to pregnancy. Musculoskeletal defects and decreased viability occurred in the offspring after injection of pregnant females.
Species: Rat
25 - 65 g/kg Reproductivity study
Result: Musculoskeletal defects and decreased viability occurred in the offspring after subcutaneous injection of pregnant females.
Species: Rabbit

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

12. Ecological information

Ecotoxicity
No data on possible environmental effects have been found.

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
D011: Waste Silver

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
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
- 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
- Clean Water Act (CWA)
  - Section 112(r) (40 CFR 68.130)
    - Priority pollutant
    - Toxic pollutant
- 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>
</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>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>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 (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

Issue date
10-04-2007

Revision date
08-21-2014

Version #
02

Material name: Silver Sulfadiazine
7226 Version #: 02 Revision date: 08-21-2014 Issue date: 10-04-2007
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Revision Information
This document has undergone significant changes and should be reviewed in its entirety.