

1. Identification

Product identifier	Silver Sulfadiazine	
Other means of identification		
Catalog number	1612608	
CAS number	22199-08-2	
Synonyms	Sulfadiazine, silver	
Chemical name	Benzenesulfonamide, 4-amino-N-2-pyrimidinyl-, monosilver (1+) salt	
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	CHEMTRAC within US & Canada	1-800-424-9300
	CHEMTRAC 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. 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. 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	Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Silver Sulfadiazine	Sulfadiazine, silver	22199-08-2	100

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 the substance is inhaled. 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. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Pharmacologically active material. Occupational exposure may cause physiological effects. 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.

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).

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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

Train employees in proper gowning and degowning practices. 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. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. 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

Powder.

Color

White. Cream.

Odor

Faint odor.

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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slightly soluble.
Solubility (other)	Acetone: Slightly soluble. Alcohol: Practically insoluble. Chloroform: Practically insoluble. Ether: Practically insoluble.
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

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. Mineral acids. Sodium hypochlorite. Calcium hypochlorite. Maleic anhydride. Nitrosyl perchlorate.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx, NOx.

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	Burning or tingling sensations. Sulfonamides: Gastrointestinal disturbances. Loss of appetite. Dizziness. Headache. Skin rash. Fever. Itching. Increased sensitivity of skin to sunlight. Sore throat. Unusual bleeding or bruising. Difficulty swallowing. Vision problems. Yellow eyes or skin. Lower back pain. Difficult or painful urination. Blood in urine. Joint pain. Muscle pain. Redness, peeling or loosening of skin. Fatigue.

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Silver Sulfadiazine (CAS 22199-08-2)		
Oral		
LD50	Mouse	> 10000 mg/kg
	Rat	> 10000 mg/kg
Skin corrosion/irritation		
Based on available data, the classification criteria are not met.		
Serious eye damage/eye irritation		
Knowledge about health hazard is incomplete.		

Local effects

1 - 20 % Skin irritation

Result: Negative.

Species: Rabbit

Test Duration: 13 weeks

Severity: Mild

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**Mutagenicity**

Ames test

Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

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: Dermal study

Result: No evidence of carcinogenicity.

Species: Mouse

Carcinogenicity: Dermal study

Result: No evidence of carcinogenicity.

Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.

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. 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

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

Result: Musculoskeletal defects and decreased viability occurred in the offspring after subcutaneous injection of pregnant females.

Species: Rabbit

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.

Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

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	D011: Waste Silver
	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.
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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Classified hazard categories

Respiratory or skin sensitization

SARA 313 (TRI reporting)

Chemical name

CAS number

% by wt.

Silver Sulfadiazine	22199-08-2	100
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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.

Clean Water Act (CWA) Section 112(r) (40 CFR 68.130)

Priority pollutant

Toxic pollutant

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (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

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

Issue date 10-04-2007

Revision date 02-10-2020

Version # 03

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