DESCRIPTION
SSD (1% Silver Sulfadiazine) Cream and SSD AF (1% Silver Sulfadiazine) Cream are topical antibacterial preparations which have as their active antimicrobial ingredient silver sulfadiazine. The active moiety is contained within an opaque, white, water miscible cream base.

Each 1000 grams of SSD/SSD AF Cream contains 10 grams of silver sulfadiazine.

Inactive Ingredients: cetyl alcohol, isopropyl myristate, polyoxyethylene steareate, propylene glycol, purified water, stearyl alcohol, sodium hydroxide, sorbitan monooleate, white petrolatum; with 0.3% methylparaben, as a preservative.

Silver sulfadiazine has the empirical formula of C$_{15}$H$_{10}$AgN$_4$O$_2$S, molecular weight of 357.14, and structural formula as shown:

\[
\text{H}_2\text{N} \quad \text{SO}_2 \quad \text{Ag} \quad \text{SO}_2 \quad \text{N}_4 \quad \text{O}_2 \quad \text{S} 
\]

CLINICAL PHARMACOLOGY
Silver sulfadiazine broad antimicrobial activity. It is bactericidal for many gram-negative and gram-positive bacteria as well as being effective against yeasts. Results from in vitro testing are listed below.

Sufficient data have been obtained to demonstrate that silver sulfadiazine will inhibit bacteria that are resistant to other antimicrobial agents and that the compound is superior to sulfadiazine.

Studies utilizing radioactive micronized silver sulfadiazine, electron microscopy, and biochemical techniques have revealed that the mechanism of action of silver sulfadiazine on bacteria differs from silver nitrate and sodium sulfadiazine. Silver sulfadiazine acts only on the cell wall to produce its bactericidal effect.

Results of In vitro Testing With 1% Concentrations of Silver Sulfadiazine
Number of Sensitive Strains/Total Number of Strains Tested

<table>
<thead>
<tr>
<th>Genus &amp; Species</th>
<th>SSD (1% Silver Sulfadiazine) Cream</th>
<th>SSD AF (1% Silver Sulfadiazine) Cream</th>
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</thead>
<tbody>
<tr>
<td>Enterobacter cloacae</td>
<td>48/50 50/50</td>
<td>48/50 50/50</td>
</tr>
<tr>
<td>Klebsiella species</td>
<td>24/24 24/24</td>
<td>24/24 24/24</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>53/54 54/54</td>
<td>53/54 54/54</td>
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<tr>
<td>Serratia species</td>
<td>63/63 63/63</td>
<td>63/63 63/63</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>27/28 28/28</td>
<td>27/28 28/28</td>
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<tr>
<td>Morganella morgani</td>
<td>53/53 53/53</td>
<td>53/53 53/53</td>
</tr>
<tr>
<td>Providencia retgeri</td>
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<td>10/10 10/10</td>
</tr>
<tr>
<td>Proteus vulgaris</td>
<td>2/2 2/2</td>
<td>2/2 2/2</td>
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<tr>
<td>Providencia species</td>
<td>1/1 1/1</td>
<td>1/1 1/1</td>
</tr>
<tr>
<td>Clostridium species</td>
<td>10/10 10/10</td>
<td>10/10 10/10</td>
</tr>
<tr>
<td>Acinetobacter calcoaceticus</td>
<td>10/10 10/10</td>
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<tr>
<td>Staphylococcus aureus</td>
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<td>100/101 101/101</td>
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<tr>
<td>Staphylococcus epidermidis</td>
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<td>51/51 51/51</td>
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<tr>
<td>β-Hemolytic Streptococcus</td>
<td>4/4 4/4</td>
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<tr>
<td>Enterococcus species</td>
<td>52/53 53/53</td>
<td>52/53 53/53</td>
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<tr>
<td>Corynebacterium diphtheriae</td>
<td>2/2 2/2</td>
<td>2/2 2/2</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>2/2 2/2</td>
<td>2/2 2/2</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>43/50 50/50</td>
<td>43/50 50/50</td>
</tr>
</tbody>
</table>

Silver sulfadiazine is not a carbonic anhydrase inhibitor and may be useful in situations where such agents are contraindicated.

INDICATIONS AND USAGE
Silver Sulfadiazine Cream is a topical antimicrobial drug indicated as an adjunct for the prevention and treatment of wound sepsis in patients with second and third degree burns.

CONTRAINDICATIONS
Silver Sulfadiazine Cream is contraindicated in patients who are hypersensitive to silver sulfadiazine or any of the other ingredients in the preparation.

Because sulfonamide therapy is known to increase the possibility of kernicterus, Silver Sulfadiazine Cream should not be used on pregnant women approaching or at term, on premature infants, or on newborn infants during the first 2 months of life.

WARNINGS
There is potential cross sensitivity between silver sulfadiazine and other sulfonamides. If allergic reactions attributable to treatment with silver sulfadiazine occur, continuation of therapy must be weighed against the potential hazards of the particular allergic reaction.

Fungal proliferation in and below the eschar may occur. However, the incidence of clinically reported fungal superinfection is low.

The use of Silver Sulfadiazine Cream in some cases of glucose-6-phosphate dehydrogenase-deficient individuals may be hazardous, as hemolysis may occur.

PRECAUTION
General: If hepatic and renal functions become impaired and elimination of drug decreases, accumulation may occur and discontinuation of Silver Sulfadiazine Cream should be weighed against the therapeutic benefit being achieved.

In considering the use of topical proteolytic enzymes in conjunction with Silver Sulfadiazine Cream, the possibility should be noted that silver may inactivate such enzymes.

Laboratory Tests: In the treatment of burn wounds involving extensive areas of the body, the serum sulfa concentrations may approach adult therapeutic levels (8 to 12 mg%). Therefore, in these patients it would be advisable to monitor serum sulfa concentrations. Renal function should be carefully monitored and the urine should be checked for sulfa crystals.

Absorption of the propylene glycol vehicle has been reported to affect osmolality, which may affect the interpretation of laboratory tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term dermal toxicity studies of 24 months duration in rats and 18 months in mice with concentrations of silver sulfadiazine three to ten times the concentration in Silver Sulfadiazine Cream revealed no evidence of carcinogenicity.

Pregnancy: Pregnancy category B.

A reproductive study has been performed in rabbits at doses up to three to ten times the concentration of silver sulfadiazine in Silver Sulfadiazine Cream and has revealed no evidence of harm to the fetus due to silver sulfadiazine. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly justified, especially in pregnant women approaching or at term (see CONTRAINDICATIONS).

Nursing Mothers: It is not known whether Silver Sulfadiazine Cream is excreted in human milk. However, sulfonamides are known to be excreted in human milk, and all sulfonamide derivatives are known to increase the possibility of kernicterus. Because of the possibility for serious adverse reactions in nursing infants from sulfonamides, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established (see CONTRAINDICATIONS).

ADVERSE REACTIONS
Several cases of transient leukopenia have been reported in patients receiving silver sulfadiazine therapy. Leukopenia associated with silver sulfadiazine administration is primarily characterized by decreased neutrophil count. Maximal white blood cell depression occurs within two to four days of initiation of therapy. Rebound to normal leukocyte levels follows onset within two to three days. Recovery is not influenced by continuation of silver sulfadiazine therapy. The incidence of leukopenia in various reports averages about 20%. A higher incidence has been seen in patients treated concurrently with corticosteroids.

Other infrequently occurring events include skin necrosis, erythema multiforme, skin discoloration, burning sensation, rashes, and interstitial nephritis.

Reduction in bacterial growth after application of topical antibacterial agents has been reported to permit spontaneous healing of deep partial-thickness burns by preventing conversion of the partial thickness to full thickness by sepsis. However, reduction in bacterial colonization has caused delayed separation, in some cases necessitating escharotomy in order to prevent contracture.

Absorption of silver sulfadiazine varies depending upon the percent of body surface area and the extent of the tissue damage. Although few have been reported, it is possible that any adverse reaction associated with sulfonamides may occur. Some of the reactions which have been associated with sulfonamides are as follows: blood dyscrasias, including agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia and hemolytic anemia; dermatologic and allergic reactions, including Stevens-Johnson syndrome and exfoliative dermatitis; gastrointestinal reactions; hepatitis and hepatocellular necrosis; CNS reactions; and toxic nephrosis.

DOSAGE AND ADMINISTRATION
FOR TOPICAL USE ONLY— NOT FOR OPHTHALMIC USE: Prompt institution of appropriate regimens for care of the burned patient is of prime importance and includes the control of shock and pain. The burn wounds are then cleansed and debrided and Silver Sulfadiazine Cream is applied under sterile conditions. The burn areas should be covered with Silver Sulfadiazine Cream at all times. The cream should be applied once to twice daily to a thickness of approximately 1/16 inch. Whenever necessary, the cream should be reapplied to any areas from which it has been removed by patient activity. Administration may be accomplished in minimal time because dressings are not required. However, if individual patient requirements make dressings necessary, they may be used. Reapply immediately after hydrotherapy.

Treatment with Silver Sulfadiazine Cream should be continued until satisfactory healing has occurred or until the burn site is ready for grafting. The drug should not be withdrawn from the therapeutic regimen while there remains the possibility of infection except if a significant adverse reaction occurs.

HOW SUPPLIED: SSD® (1% Silver Sulfadiazine) Cream: white to off-white cream.

50 gram jar
400 gram jar

25 gram tube
50 gram tube
85 gram tube

SSD AF® (1% Silver Sulfadiazine) Cream: white to off-white cream.

50 gram jar
400 gram jar

*Alternate Formula

Store at controlled room temperature 15°-30°C (59°-86°F).

Manufactured for Par Pharmaceutical, Inc.
Spring Valley, NY 10977
Manufactured by BASF Corporation
Mount Olive, NJ 07828
Rev. 05/99
Material Safety Data Sheet
Silver sulfadiazine MSDS

Section 1: Chemical Product and Company Identification

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>Silver sulfadiazine</th>
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<tr>
<td>Catalog Codes:</td>
<td>SLS4525, SLS2311</td>
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<tr>
<td>CAS#:</td>
<td>22199-08-2</td>
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<tr>
<td>RTECS:</td>
<td>WP1950000</td>
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<tr>
<td>Chemical Name:</td>
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</tr>
<tr>
<td>Chemical Formula:</td>
<td>C10H9AgN4O2S</td>
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</table>

Contact Information:
Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396
US Sales: 1-800-901-7247
International Sales: 1-281-441-4400
Order Online: ScienceLab.com
CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300
International CHEMTREC, call: 1-703-527-3887
For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS #</th>
<th>% by Weight</th>
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</thead>
<tbody>
<tr>
<td>Silver sulfadiazine</td>
<td>22199-08-2</td>
<td>100</td>
</tr>
</tbody>
</table>

Toxicological Data on Ingredients: Silver sulfadiazine: ORAL (LD50): Acute: 10001 mg/kg [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Very hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion. Hazardous in case of inhalation. Inflammation of the eye is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering.

Potential Chronic Health Effects:
Very hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion. Hazardous in case of inhalation.
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.
## Section 4: First Aid Measures

**Eye Contact:** Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.

**Skin Contact:**
After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

**Serious Skin Contact:**
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

**Inhalation:** Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

**Serious Inhalation:** Not available.

**Ingestion:**
Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

**Serious Ingestion:** Not available.

## Section 5: Fire and Explosion Data

**Flammability of the Product:** May be combustible at high temperature.

**Auto-Ignition Temperature:** Not available.

**Flash Points:** Not available.

**Flammable Limits:** Not available.

**Products of Combustion:** These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...). Some metallic oxides.

**Fire Hazards in Presence of Various Substances:** Not available.

**Explosion Hazards in Presence of Various Substances:**
Risks of explosion of the product in presence of mechanical impact: Not available.
Risks of explosion of the product in presence of static discharge: Not available.

**Fire Fighting Media and Instructions:**
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

**Special Remarks on Fire Hazards:** Not available.

**Special Remarks on Explosion Hazards:** Not available.

## Section 6: Accidental Release Measures

**Small Spill:**
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

**Large Spill:**
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system. Be careful that the product is not
Section 7: Handling and Storage

**Precautions:**
Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

**Storage:**
Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

Section 8: Exposure Controls/Personal Protection

**Engineering Controls:**
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Personal Protection:**
Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

**Personal Protection in Case of a Large Spill:**
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

**Exposure Limits:**
TWA: 0.01 (mg/m3) from ACGIH
Consult local authorities for acceptable exposure limits.

Section 9: Physical and Chemical Properties

**Physical state and appearance:** Solid. (Powdered solid.)

**Odor:** Slight.

**Taste:** Not available.

**Molecular Weight:** 357.13 g/mole

**Color:** White.

**pH (1% soln/water):** Not applicable.

**Boiling Point:** Not available.

**Melting Point:** Not available.

**Critical Temperature:** Not available.

**Specific Gravity:** Not available.

**Vapor Pressure:** Not applicable.
Vapor Density: Not available.

Vatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Insoluble in cold water.

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**Section 10: Stability and Reactivity Data**

**Stability**: The product is stable.

**Instability Temperature**: Not available.

**Conditions of Instability**: Not available.

**Incompatibility with various substances**: Not available.

**Corrosivity**: Non-corrosive in presence of glass.

**Special Remarks on Reactivity**: Not available.

**Special Remarks on Corrosivity**: Not available.

**Polymerization**: No.

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**Section 11: Toxicological Information**

**Routes of Entry**: Eye contact. Inhalation. Ingestion.

**Toxicity to Animals**: Acute oral toxicity (LD50): 10001 mg/kg [Rat].

**Chronic Effects on Humans**: Not available.

**Other Toxic Effects on Humans**: Very hazardous in case of skin contact (irritant), of ingestion. Hazardous in case of inhalation.

**Special Remarks on Toxicity to Animals**: Not available.

**Special Remarks on Chronic Effects on Humans**: Not available.

**Special Remarks on other Toxic Effects on Humans**: Not available.

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**Section 12: Ecological Information**

**Ecotoxicity**: Not available.

**BOD5 and COD**: Not available.

**Products of Biodegradation**: Possibly hazardous short term degradation products are not likely. However, long term degradation products may
Toxicity of the Products of Biodegradation: The products of degradation are more toxic.

Special Remarks on the Products of Biodegradation: Not available.

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**Section 13: Disposal Considerations**

Waste Disposal:

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**Section 14: Transport Information**

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

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**Section 15: Other Regulatory Information**

Federal and State Regulations: TSCA 8(b) inventory: No products were found.


Other Classifications:

WHMIS (Canada): CLASS D-2B: Material causing other toxic effects (TOXIC).

DSCL (EEC):
R38- Irritating to skin.
R41- Risk of serious damage to eyes.

HMIS (U.S.A.):

Health Hazard: 2
Fire Hazard: 1
Reactivity: 0
Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2
Flammability: 1
Reactivity: 0
Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.
### Section 16: Other Information

<table>
<thead>
<tr>
<th><strong>References:</strong></th>
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