

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078933328

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078939084 078944617 078944620

## SAFETY DATA SHEET

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**Manufactured for:** Ascend Laboratories, LLC Parsippany, NJ 07054  
**Manufactured by:** Crown Laboratories, Inc. Johnson City, TN 37604  
**Emergency Telephone No.:** Contact poison control center  
**Customer Service No.:** 1-877-272-7901 or 1-800-877-8869

### SECTION 1: IDENTIFICATION

Product Name:	Silver Sulfadiazine Cream, USP 1%
Synonyms:	Burn Cream.
NDC:	67877-124-20, 67877-124-25, 67877-214-05, 67877-124-50, 67877-124-85, 67877-124-40
CAS #:	Not applicable.
Chemical Family:	Sulfonamide.
Formula:	Silver Sulfadiazine (micronized) 1% in a hydrophilic (water dispersible) base consisting of Purified Water, Stearyl Alcohol, White Petrolatum, Polyoxyl 40 Stearate, Propylene Glycol USP, Isopropyl Myristate NF, Sorbitan Monooleate NF, with 3% Methylparaben NF as a preservative.

### SECTION 2: HAZARD IDENTIFICATION

**According to Regulations of 2012 OSHA Hazard Communications Standard; 29 CFR Part 1910.1200**

#### Classification of the product

No need for classification according to GHS criteria for this product.

#### Labeling elements

This product does not require a hazard warning label in accordance with GHS criteria.

#### Hazards not otherwise classified

No specific dangers are known, if the directions for use and storage on the label are followed.

#### Emergency overview

No particular hazards are known. Avoid contact with eyes (could be an irritant to the eyes.)

**SECTION 3: COMPOSITION / INGREDIENT INFORMATION**

NAME	CAS#	CARCINOGEN			HAZARD DATA	
		IARC	NTP	OSHA	ACGIH TLV	OSHA PEL
Silver Sulfadiazine	22199-08-2	No	No	No	NE	NE
Purified Water	7732-18-5	No	No	No	NE	NE
Stearyl Alcohol	112-92-5	No	No	No	NE	NE
White Petrolatum	8009-03-8	No	No	No	NE	NE
Polyoxyl 40 Stearate	9004-99-3	No	No	No	NE	NE
Propylene Glycol	57-55-6	No	No	No	NE	NE
Isopropyl Myristate	110-27-0	No	No	No	NE	NE
Sorbitan Monooleate	1338-43-8	No	No	No	NE	NE
Methylparaben	99-76-3	No	No	No	NE	NE

NE = Not Established

**SECTION 4: FIRST AID PROCEDURES**

Eyes:	Flush eyes with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
Skin:	Wash affected area thoroughly with soap and water. If irritation develops, seek medical attention.
Ingestion:	Contact a Poison Control Center right away
Inhalation:	Not applicable. Product is not an inhalation hazard.
Symptoms & Effects	No hazard is expected under intended use and appropriate handling of this product CALL A PHYSICIAN. CONTACT A POISON CONTROL CENTER.

**SECTION 5: FIRE FIGHTING MEASURES**

Flash Point:	Not applicable.
Auto-ignition Temperature °F:	Not applicable.
Flammable Limits in Air by Volume LEL:	Not applicable.
UEL:	Not applicable.
Extinguishing Media:	Alcohol foam, Dry chemical, Carbon dioxide.
Special Fire Fighting Procedures:	Use self-contained breathing apparatus and protective clothing.
Unusual Fire and Explosion Hazards:	May react with strong oxidizers and extreme heat.

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**SECTION 6: ACCIDENTAL RELEASE MEASURES**

Respiratory Protection:	No special precautions necessary. General ventilation.
Skin Protection:	Normal hygiene.
Eye Protection:	Normal hygiene.
Other Protective Clothing or Equipment:	As needed to prevent repeated/prolonged contact.
Environmental Precautions:	Care should be taken to avoid environmental release. This product is not regulated by RCRA.

**SECTION 7: HANDLING AND STORAGE**

Precautions to be taken in Handling/Storage:	Keep container closed when not in use. Do not handle or store near heat, flame or oxidizers.
Hygienic Practices:	Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin. Use general ventilation to protect your lungs. Do not wear contaminated clothing until thoroughly laundered.
When Material is Released or Spilled:	Assure slippery conditions are nullified. Use absorbents, scoop up and remove. Wash area with soap and water. Dispose of in accordance with federal, state and local regulations.
Waste Disposal Methods:	Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

**SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION**

Primary Route(s) of Entry:	Dermal, topical
<u>Signs and Symptoms of Exposure</u>	
Overexposure Effects:	Possible skin irritation or allergic reactions in sensitive individuals.
b. Chronic Effects:	Systemic absorption may cause effects similar to overexposure.
1. Inhalation:	Not likely due to the physical state of the product.
2. Eyes:	Will cause irritation. Not for ophthalmic use.
3. Skin:	System absorption may cause effects similar to overexposure.
4. Ingestion:	Unknown. May cause allergic reaction or irritation in sensitive individuals.
5. Medical Conditions	
Potentially Aggravated:	May cause allergic reaction and skin irritation.



**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

Appearance and Odor:	White to off white cream with characteristic odor.
Molecular Weight:	Not applicable.
pH:	Not determined.
Refractive Index @ 20° C:	Not applicable.
Viscosity @ 25° C:	No applicable.
Boiling Point:	Not determined.
Freezing/Melting Point:	Not determined.
Congeeing Point:	Not determined.
Vapor Pressure (mm Hg @ 20°C):	Not determined.
Vapor Density (Air=1):	Not determined.
Solubility in Water:	Disperses.
Solubility in Alcohol:	Partially soluble.
Solubility in Oil:	Partially soluble.
Solubility in Other:	Not applicable.
Specific Gravity (H <sub>2</sub> O=1):	Not determined
% Volatile by Volume:	Not determined.
Evaporation Rate (Ether=1):	Not determined.

**SECTION 10: STABILITY AND REACTIVITY**

Stability:	(X) Stable ( ) Unstable
Conditions and Chemicals to Avoid:	Avoid strong oxidizers, strong acids, bases and sources of heat.
Hazardous Combustion or Decomposition Products:	May emit toxic fumes.
Hazardous Polymerization:	( ) May Occur (X) Will Not Occur

**SECTION 11: TOXICOLOGICAL INFORMATION**

See Section 4 for First Aid Measures for specific routes of exposure

See Section 3 for ingredient information. No numerical measures of toxicity are available

**SECTION 12: ECOLOGICAL INFORMATION**

Aquatic Toxicity:	Not indicated.
Biodegradability:	Not indicated.

**SECTION 13: DISPOSAL CONSIDERATIONS**

Assure disposal is performed in accordance with applicable local, state, and federal regulations.

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**SECTION 14: TRANSPORTATION INFORMATION**

<b>Land Transport USDOT</b>	Not classified as a dangerous good under transportation regulations
<b>Sea Transport IMDG</b>	Not classified as a dangerous good under transportation regulations
<b>Air Transport IATA/ICAO</b>	Not classified as a dangerous good under transportation regulations

**SECTION 15: REGULATORY INFORMATION**

Refer to the following references:

OSHA Regulations:	If respirator used, 29 CFR 1910.134
DOT Regulations:	Not applicable.
EPA Regulations:	Not applicable
Other:	None

**SECTION 16: OTHER INFORMATION**

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Effective Date: 03-08-2019	Revision # 00	Replaces None
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