



Monarch Pharmaceuticals, Inc.
501 Fifth Street
Bristol, Tennessee 37620
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MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, Monarch Pharmaceuticals makes no representations or warranties, either expressed or implied, and assumes no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information.

SECTION I MATERIAL IDENTIFICATION

PRODUCT NAME: Silvadene@Cream

DATE OF ISSUE: 04-24-03

FORMULA: N'-2-Pyrimidinylsulfanilamide monosilver(1+) Salt

SUPERSEDES: N/A

NDC#: 61570-131-20 20gm tube
61570-131-85 85 gm tube
61570-131-50 50 gm jar
61570-131-40 400 gm jar
61570-131-98 1000 gm jar

REVISION: 11/02/05

SYNONYMS: Silver Sulfadiazine

MANUFACTURING DIVISION:

ADDRESS
501 Fifth Street
Bristol, TN 37620

PERSON TO CONTACT **PHONE #**
Bill Smith 423-989-8042

SECTION II INGREDIENT (S)

EXPOSURE LIMITS/GUIDELINES

CAS#	INGREDIENT NAME	OSHA PEL	ACGIH TLV	OTHER	LISTED AS CARCINOGEN
N/D	Micronized silver sulfadiazine	N/D	N/D	N/D	No

SECTION III PHYSICAL AND CHEMICAL DATA

PHYSICAL STATE: Cream

APPEARANCE: White

CHARACTERISTIC ODOR: N/A

SPECIFIC GRAVITY: N/D

SOLUBILITY IN WATER: Soluble

ph: N/A

SECTION IV FIRE AND EXPLOSION DATA

FLASH POINT AND METHOD: N/A

EXTINGUISHING MEDIUM: Carbon Dioxide, Dry Chemical Powder, Alcohol or Polymer Foam. Water may be effective for cooling.

SPECIAL FIRE FIGHTING PROCEDURES: N/D

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: None

SECTION V**CHEMICAL REACTIVITY DATA**

STABILITY: Material is stable under normal conditions. **INCOMPATIBILITY:** N/A

HAZARDOUS POLYMERIZATION: Will not occur. **HAZARDOUS DECOMPOSITION OF BYPRODUCTS:** N/A

CONDITIONS TO AVOID: N/D

SECTION VI**HEALTH HAZARD INFORMATION****ROUTE OF ENTRY:**

1. **Inhalation:** Under normal conditions exposure to this material by inhalation is not expected to occur.
2. **Skin Contact:** 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.
3. **Ingestion:** Under normal conditions exposure to this material by ingestion is not expected to occur.

HEALTH HAZARD: N/D

TOXICITY INFORMATION:

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 SILVADENE Cream 1% revealed no evidence of carcinogenicity. A reproductive study has been performed in rabbits at doses up to three to ten times the concentration of silver sulfadiazine in SILVADENE Cream 1% 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.

(For further information see current package insert)

SECTION VII**FIRST AID INFORMATION**

EYES: Should be removed from eye as soon as possible by irrigation with water.

SKIN: Can be washed off readily with water.

INHALATION: N/D

INGESTION: N/D

REGULATED EXPOSURE LIMITS: N/D

SECTION VIII**SPECIAL PROTECTION INFORMATION**

RESPIRATORY PROTECTION: N/A

PROTECTIVE GLOVES: Latex

VENTILATION: N/A

EYE PROTECTION: N/A

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: N/A

SECTION IX**SPILL, LEAK, AND DISPOSAL PROCEDURES**

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED: Wear protective equipment. Shovel or sweep up spill. Place in DOT approved container and seal.

WASTE DISPOSAL METHOD: Dispose of as a medical waste in accordance with local, state and federal regulations or the authority having jurisdiction.

SECTION X**SPECIAL PRECAUTIONS**

STORE AS STATED IN PRODUCT LABELING: Store in a dry location at room temperature (59-86 DEG F, 15-30 DEG C).

NA-NOT APPLICABLE**ND-NOT DETERMINED**

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.