1. PRODUCT IDENTIFICATION

TRADE/MATERIAL NAME: SILVER SULFADIAZINE 1% CREAM
Silver Sulfadiazine Cream 1% 25 g and 85 g Tubes, Silver Sulfadiazine Cream 1% 50 g and 400 g Jars

DESCRIPTION: Silver Sulfadiazine Cream
OTHER DESIGNATIONS: NDC# 00591-0810-83, 00591-0810-85, 00591-0810-46, 00591-0810-55
CHEMICAL NAME: 4-Amino-N-2-pyrimidinyl-benzenesulfonamide Monosilver(1+) Salt
CHEMICAL FAMILY: Sulfonamide Antibiotic
HOW SUPPLIED: 1% cream in 25 g and 85 g tubes and 1% cream in 50 g and 400 g jars
FORMULA: C₁₀H₉AgO₂S

PRODUCT USE: Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER’S NAME: ACTAVIS
400 Interpace Parkway, Morris Corporate Center III Parsippany, NJ 07054, USA
e-mail: SDS@actavis.com
BUSINESS PHONE/GENERAL MSDS INFORMATION: 1-800-272-5525
EMERGENCY PHONE (U.S./NORTH AMERICA): CHEMTREC: 1-800-424-9300
EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: 1-703-527-3887

2. COMPOSITION and INFORMATION ON INGREDIENTS


EU CLASSIFICATION: Irritant [Xi]
EU RISK PHRASES: [R: 43] May cause sensitization by skin contact. (See Section 15 for details on classification)

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/v</th>
<th>EU CLASSIFICATION FOR COMPONENTS</th>
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</thead>
<tbody>
<tr>
<td>Silver Sulfadiazine</td>
<td>22199-08-2</td>
<td>244-834-5</td>
<td>1%</td>
<td>HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.</td>
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<tr>
<td>Isopropyl Myristate</td>
<td>110-27-0</td>
<td>203-751-4</td>
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<td>HAZARD CLASSIFICATION: Xi [Irritant] RISK PHRASES: R: 36/37/38</td>
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<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>0.3%</td>
<td>HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.</td>
</tr>
<tr>
<td>Polyoxyl 40 Stearate</td>
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<td>215-665-4</td>
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<td>HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.</td>
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<tr>
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<td>231-791-2</td>
<td>Proprietary</td>
<td>HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.</td>
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<td>8009-03-8</td>
<td>232-373-2</td>
<td>Proprietary</td>
<td>HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.</td>
</tr>
</tbody>
</table>

See Section 15 for full EU classification information of product and components.
NOTE: ALL Canadian WHMIS required information is included in appropriate sections based on the ANSI Z400.1-1998 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR. The MSDS is also prepared to include all European Union required information under EU Directives.
3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:
Product Description: This product is supplied as a white cream.

Health Hazards: The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin. Silver Sulfadiazine (the active component in this product) is a possible reproductive toxin. Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Silver Sulfadiazine may experience allergic reactions to this product. Therapeutic use of this product can cause adverse symptoms on the central nervous system, eyes, skin, blood system.

Flammability Hazards: When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:
The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Due to the formulation of this product, inhalation is not a significant route of occupational overexposure. Inhalation of airborne mists or sprays of this product may slightly irritate the nose, throat, and lungs.

CONTACT WITH SKIN or EYES: Contact with the skin may cause irritation in sensitive individuals. Symptoms can include pain, burning, itching, unusual bleeding or bruising, fever, sore throat, yellowing of the skin or eyes, blood in urine, aching joints, unusual weakness or tiredness, skin rash. Contact with the eyes of this product may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: 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; central nervous system reactions; and toxic nephrosis. Other side effects described in "Other Potential Health Effects" are rare but may be induced by prolonged or repeated skin contact.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for "Other Potential Health Effects".

INJECTION: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms from prolonged or repeated exposure may include those described for "Other Potential Health Effects".
3. HAZARD IDENTIFICATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included:

Common symptoms that may occur from therapeutic use of this product include burning feeling on treated area. Less common or rare symptoms can include brownish-gray skin discoloration, itching or skin rash. Rarely, the following symptoms can include: blisters, peeling or loosening of skin, bloody or cloudy urine, chills or fever, cough, decreased amount of urine or less frequent urination, increased sensitivity of skin to sunlight, especially in patients with burns on large areas, intense itching of burn wounds, pain at site of application, painful or difficult urination, red skin lesions, often with a purple center, shortness of breath, sore throat, sores, ulcers or white spots on lips or in mouth, swollen glands, unusual bleeding or bruising, unusual tiredness or weakness.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin, with the possibility of burning sensation in area of contamination, itching, rash and discoloration of the skin.

CHRONIC: In the event of chronic exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result. Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Silver Sulfadiazine may experience allergic reactions to this product. Silver Sulfadiazine (the active component in this product) is a possible reproductive toxin, based on animal tests. See Section 11 (Toxicological Information, for additional information).

TARGET ORGANS: ACUTE: Industrial Exposure: Skin, eyes. Therapeutic Doses: Skin. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Central nervous system, eyes, skin, kidneys, liver or blood system.

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

SKIN EXPOSURE: Basic hygiene should prevent any problems. If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes. Victims must seek medical attention, especially if an adverse reaction occurs.

EYE EXPOSURE: If this product enters the eyes, open victim’s eyes while under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If mists or sprays of this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions including blood problems, glucose-6-phosphate dehydrogenase deficiency (lack of G6PD enzyme), kidney disease or, liver disease, porphyria, may be aggravated by chronic overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable.
Upper (UEL): Not applicable.
5. FIRE-FIGHTING MEASURES (Continued)

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.
- Water Spray: OK
- Carbon Dioxide: OK
- Dry Chemical: OK
- Halon: OK
- Foam: OK
- Other: Any "ABC" Class

UNUSUAL FIRE AND EXPLOSION HAZARDS: When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides).
- Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with soapy water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: For small releases of this compound (1 jar or tube), take basic hygiene precautions. Lightweight gloves, a lab coat, and eye protection should be worn. Wipe up spilled material, place in a bag, and hold for waste disposal. In case of a large spill, clear the affected area and protect people. Large or uncontrolled releases (a case of product) should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including lab gloves, full body gown, boots, and splash goggles. Respiratory protection should not be necessary. Wipe up spilled material. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces.

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. Use of this product should meet the provisions outlined as follows.
- Work should be performed in an appropriate, designated area;
- Contaminated waste must be properly handled; and,
- If necessary, work areas must be regularly decontaminated.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container. Inspect bottles containing this product for leaks or damage.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.
8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

<table>
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<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>ACGIH-TLVs</th>
<th>OSHA-PELs</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>AIHA WEELs</th>
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</thead>
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<tr>
<td></td>
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<td>TWA</td>
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<td>Silver Sulfadiazine</td>
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<td>NE</td>
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<td>NE</td>
<td>NE</td>
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</tr>
</tbody>
</table>

NE = Not Established. See Section 16 for Definition of Terms

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently, there are no international exposure limits for components of this product.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, and EU member states. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure-demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHAs Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133, the European Standard EN166 and appropriate Standards of Canada for further information.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138, and appropriate Standards of the EU and Canada for further information.

BODY PROTECTION: During patient administration, use of light-weight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee’s feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not applicable for product.
FREEZING/MELTING POINT: Not established.
EVAPORATION RATE (nBuAc = 1): Not established.
SOLUBILITY IN WATER: Not soluble.
VAPOR PRESSURE (air = 1): Not applicable for product.
SPECIFIC GRAVITY (water = 1): Not applicable.
ODOR THRESHOLD: Not established.
pH: Not established.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
APPEARANCE AND COLOR: This product is supplied as a white cream.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product is a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: This product is stable.
DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides).
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.
HAZARDOUS POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.
11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to prescription as well as to over-the-counter products containing Silver Sulfadiazine may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following:

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 white blood cell count. Maximal white blood cell depression occurs within 2 to 4 days of initiation of therapy. Rebound to normal leukocyte levels follows onset within 2 to 3 days. Recovery is not influenced by continuation of Silver Sulfadiazine therapy. An increased incidence of leukopenia has been reported in patients treated concurrently with cimetidine.

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; central nervous system reactions; and toxic nephrosis.

Fungal proliferation in and below the eschar may occur. However, the incidence of clinically reported fungal super-infection is low. The use of Silver Sulfadiazine cream 1% in some cases of glucose-6-phosphate dehydrogenase-deficient individuals may be hazardous, as hemolysis may occur.

IRRITANCY OF PRODUCT: This product can irritate contaminated tissue if contact can occur.

SENSITIZATION OF PRODUCT: 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; central nervous system reactions; and toxic nephrosis.

TOXICITY DATA: The following are toxicity data for the active component of this product, Silver Sulfadiazine. This MSDS presents human and Oral-Rat toxicity data currently available for the active component. Additional data are available for the active component and data are available for other components of this product, but are not presented in this MSDS. Contact Watson Pharmaceuticals for more information.

SILVER SULFADIAZINE:
- **LD₅₀ (Oral-Rat)** > 10 gm/kg
- **SILO (Skin-Man)** 536 mg/kg/21 weeks-intermittent: Peripheral Nerve and Sensation: flaccid paralysis without anesthesia (usually neuromuscular blockage)

SUSPECTED CANCER AGENT: 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 1% revealed no evidence of carcinogenicity.

ACGIH lists Stearates such as PEG-40 Stearate as TLV-A4 (Not Classifiable as Human Carcinogen). The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system. Silver Sulfadiazine is rated as a Pregnancy Category B (NO EVIDENCE OF RISK, Human evidence is negative, but animal evidence is positive. Alternately, there is no human evidence and animal evidence is negative.) The reproductive effects described are related to therapeutic use of this product and are not reported to occur from industrial handling and exposure.

- **Mutagenicity:** Currently, there are no mutagenic effects reported for the active ingredient, Silver Sulfadiazine.
- **Embryotoxicity:** This product is not reported to be embryotoxic to humans in therapeutic doses.
- **Teratogenicity:** 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 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.
### 11. TOXICOLOGICAL INFORMATION (Continued)

**REPRODUCTIVE TOXICITY INFORMATION**  
Reproductive Toxicity: Reproductive studies have not been done in humans with Silver Sulfadiazine. However, sulfa medicines may increase the chance of liver problems in newborn infants. It is not known whether Silver Sulfadiazine 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.

A *mutagen* is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An *embryo toxin* is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A *teratogen* is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A *reproductive toxin* is any substance that interferes in any way with the reproductive process.

**ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs):** Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

### 12. ECOLOGICAL INFORMATION

**ENVIRONMENTAL STABILITY:** The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

**EFFECT OF MATERIAL ON PLANTS or ANIMALS:** No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.

**EFFECT OF CHEMICAL ON AQUATIC LIFE:** No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

### 13. DISPOSAL CONSIDERATIONS

**PREPARING WASTES FOR DISPOSAL:** Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

**U.S. EPA WASTE NUMBER:** Not applicable to wastes consisting only of this product.

### 14. TRANSPORTATION INFORMATION

**THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.**

**PROPER SHIPPING NAME:** Not Regulated

**HAZARD CLASS NUMBER and DESCRIPTION:** Not Applicable

**UN IDENTIFICATION NUMBER:** Not Applicable

**PACKING GROUP:** Not Applicable

**DOT LABEL(S) REQUIRED:** Not Applicable

**EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004):** Not Applicable

**MARINE POLLUTANT:** No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

**TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS:** This product is not considered as Dangerous Goods, per regulations of Transport Canada.

**INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:** This product is not considered as Dangerous Goods by the International Maritime Organization.

**EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR):** This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

### 15. REGULATORY INFORMATION

**UNITED STATES REGULATIONS:**

**U.S. SARA REPORTING REQUIREMENTS:** The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
15. REGULATORY INFORMATION (Continued)

UNITED STATES REGULATIONS (continued):

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 Lists.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE SKIN AND EYE IRRITATION. MAY CAUSE ALLERGIC REACTION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting—seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO₂, or “alcohol” foam. IN CASE OF SPILL: Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: Class D2B (Materials Causing Other Toxic Effects)

EUROPEAN UNION REGULATIONS:


EU CLASSIFICATION: Irritant [Xi].

EU RISK PHRASES: [R: 43] May cause sensitization by skin contact.

EU SAFETY PHRASES: [S: (2-)] Keep out of reach of children. (This safety phrase can be omitted from the label when the substance or preparation is sold for industrial use only.) [S: 36/37] Wear suitable protective clothing and gloves. [S: 45] In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

EUROPEAN UNION ANNEX II HAZARD SYMBOL:

EU INFORMATION FOR COMPONENTS:

Isopropyl Myristate:

EU EINECS/ELINCS NUMBER: 253-149-0
EU CLASSIFICATION: This compound meets the definition of Xi, Irritant as defined by the European Union Council Directives 67/548/EEC and 2001/59/EC.
EU RISK PHRASES: [R: 36/37/38] Irritating to eyes, respiratory system, and skin.
EU SAFETY PHRASES: [S: 24/25] Avoid contact with skin and eyes. [S: 26] In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. [S: 36/37/39] Wear suitable protective clothing, gloves, and eye/face protection.
15. REGULATORY INFORMATION (Continued):

EU INFORMATION FOR COMPONENTS (continued):

- **Methylparaben**: EU EINECS/ELINCS NUMBER: 202-785-7
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

- **PEG-40 Stearate**: EU EINECS/ELINCS NUMBER: Unlisted
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

- **Propylene Glycol**: EU EINECS/ELINCS NUMBER: 200-338-0
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

- **Silver Sulfadiazine**: EU EINECS/ELINCS NUMBER: 244-834-5
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

- **Sorbitan Monoleate**: EU EINECS/ELINCS NUMBER: 215-665-4
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

- **Stearyl Alcohol**: EU EINECS/ELINCS NUMBER: 204-017-6
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

- **White Petrolatum**: EU EINECS/ELINCS NUMBER: 232-373-2
- **EU CLASSIFICATION**: An official classification for this substance has not been published in Commission Directives.

16. OTHER INFORMATION

This Safety Data Sheet is offered pursuant to OSHA’s Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Watson Laboratories, Inc. knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

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DEFINITION OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

- **CAS #**: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

**EXPOSURE LIMITS IN AIR:**

- **CEILING LEVEL**: The concentration that shall not be exceeded during any part of the working exposure.

- **DFG MAK Pregnancy Risk Group Classification**: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. Group B: Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. Group C: There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. Group D: Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

- **IDLH-Immediately Dangerous to Life and Health**: This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

- **LOQ**: Limit of Quantitation.

- **MAK**: Federal Republic of Germany Maximum Concentration Values in the workplace.

- **NE**: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

- **NIC**: Notice of Intended Change.

- **NIOSH CEILING**: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

- **NIOSH RELs**: NIOSH’s Recommended Exposure Limits.

**EXPOSURE LIMITS IN AIR (continued):**

- **PEL-Permissible Exposure Limit**: OSHA’s Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, “Vacated 1989 PEL,” is placed next to the PEL that was vacated by Court Order.

- **SKIN**: Used when there is a danger of cutaneous absorption.

- **STEL-Short Term Exposure Limit**: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

- **TLV-Threshold Limit Value**: An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

- **TWA-Time Weighted Average**: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

- **HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS**: This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

- **HEALTH HAZARD**:
  - **0 (Minimal Hazard)**: No significant health risk, irritation of skin or eyes not anticipated. **Skin Irritation**: Essentially non-irritating. PII or Draize = “0”. **Eye Irritation**: Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = “0”. **Oral Toxicity LDo50 Rat**: < 5000 mg/kg. **Dermal Toxicity LDo50 Rat or Rabbit**: < 2000 mg/kg. **Inhalation Toxicity 4-hrs LDo50**: < 20 mg/L. **1 (Slight Hazard)**: Minor reversible injury may occur; slightly or mildly irritating. **Skin Irritation**: Slightly or mildly irritating. **Eye Irritation**: Slightly or mildly irritating. **Oral Toxicity LDo50 Rat**: > 500-2000 mg/kg. **Dermal Toxicity LDo50 Rat or Rabbit**: > 1000-2000 mg/kg. **Inhalation Toxicity LDo50 4-hrs**: > 2-20 mg/L.**
HAZARDOUS MATERIALS IDENTIFICATION SYSTEM
HAZARD RATINGS (continued):

DEFINITION OF TERMS (Continued):

PHYSICAL HAZARD:

0 (Water Reactivity: Materials that do not react with water. Organic Peroxides: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react violently with water, but will not release energy. Explosives: Division 1.5 & 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. Compressed Gases: Pressure below OSHA definition. Pyrophorics: No Rating. Oxidizers: Packaging Group III: Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. Unstable Reactives: Substances that may decompose, condense or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosive hazard. Substances that readily undergo hazardous polymerization in the absence of initiators.; 1 (Water Reactivity: Materials that may react violently with water. Organic Peroxides: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. Explosives: Division 1.4 – Explosive substances where the explosive effect are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. Compressed Gases: Pressurized and OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. Pyrophorics: No Rating. Oxidizers: Packing Group II: Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 sodium chloride solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature); 2 (Water Reactivity: Materials that may form explosive reactions with water. Organic Peroxides: Materials that are capable of detonation or self-explosion, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. Explosives: Division 1.2 – Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. Compressed Gases: Pressure > 514.7 psi absolute at 21.1°C (70°F) [500 psig]. Pyrophorics: No Rating. Oxidizers: Packing Group I: Solids: any material that, either in concentration tested, exhibits a mean burning time less than the mean burning time of a 2:3 potassium bromate/cellulose mixture. Liquids: Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. Unstable Reactives: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.; 4 (Water Reactivity: Materials that react explosively with water without requiring heat or confinement. Organic Peroxides: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. Explosives: Division 1.1 & 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. Compressed Gases: No Rating. Pyrophorics: Add to the definition of Flammability “4. Oxidizers: No “4” rating. Unstable Reactives: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.);
DEFINITION OF TERMS (Continued)

TOXICOLOGICAL INFORMATION:
Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: LD₅₀ - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; LC₅₀ - Lethal Concentration (gases) which kills 50% of the exposed animals; ppm concentration expressed in parts of material per million parts of air or water; mg/m³ concentration expressed in weight of substance per volume of air; mg/kg quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include TDL₀, the lowest dose to cause a symptom and TCLo the lowest concentration to cause a symptom; TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo, the lowest dose (or concentration) to cause lethal or toxic effects. Cancer Information: The sources are: IARC - the International Agency for Research on Cancer; NTP - the National Toxicology Program; RTECS - the Registry of Toxic Effects of Chemical Substances; OSHA and CAL/OSHA. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. Other Information: BEI - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

ECOLOGICAL INFORMATION:
EC is the effect concentration in water. BCF = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. TCₘ₀ = median threshold limit; Coefficient of Oil/Water Distribution is represented by log Kₐw or log Koc and is used to assess a substance’s behavior in the environment.

REGULATORY INFORMATION:
U.S. and CANADA:
This section explains the impact of various laws and regulations on the material. EPA is the U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits. NIOSH is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). WHMIS is the Canadian Workplace Hazardous Materials Information System. DOT and TC are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Domestic Substances List (DSL/NDSL); the U.S. Toxic Substance Control Act (TSCA); Marine Pollutant status according to the DOT; the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations. This section also includes information on the precautionary warnings which appear on the material’s package label. OSHA - U.S. Occupational Safety and Health Administration.

EUROPEAN: EU is the European Union (formerly known as the EEC, European Economic Community). EINECS: This the European Inventory of Now-Existing Chemical Substances. The ARD is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the RID are the International Regulations Concerning the Carriage of Dangerous Goods by Rail. AUSTRALIAN: AICS is the Australian Inventory of Chemical Substances. NOHSC: National Occupational Health & Safety Code.