SAFETY DATA SHEETS

This SDS packet was issued with item: 078444656

N/A

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Altana

BACITRACIN-NEOMYCIN-POLYMYXIN STERILE OPHTHALMIC OINTMENT

MANUFACTURER'S NAME: ALTANA INC. - BYK PHARMACEUTICAL GROUP E. FOUGERA & COMPANY DIVISION PHARMADERM DIVISION SAVAGE LABORATORIES DIVISION 60 BAYLIS ROAD MELVILLE, NEW YORK 11747 EMERGENCY TELEPHONE NO.: (516) 454-7677 (Business Hours) (516) 454-7692 (Other Times) SECTION 1: IDENTITY _____ PRODUCT NAME: Bacitracin-Neomycin-Polymyxin Sterile Ophthalmic Ointment SYNONYMS: "Triple" Antibiotic Ointment CAS #: Not applicable CHEMICAL FAMILY: Antibacterials in petrolatum. FORMULA: Less than 1% each of the antibacterials in petrolatum. Ophthalmic ointment also contains mineral oil. _____ SECTION 2: SAFETY AND HAZARD RATINGS _____ _____ HEALTH (Acute-Chronic): 1-1 FLAMMABILITY: 1 REACTIVITY: 0 ENVIRONMENT (Air-Water-Soil): 0-0-3 SPECIAL HAZARDS: None PROTECTIVE EQUIPMENT: General ventilation, eye and hand wash. RATINGS: MINIMAL: 0 SLIGHT: 1 MODERATE: 2 SEVERE: 3 EXTREME: 4 SECTION 3: EMERGENCY AND FIRST AID PROCEDURES EYES: Flush eyes with copious amounts of water for at least 15 minutes.(Non-ophthalmic form only.) SKIN: Wash with soap and water. INGESTION: Induce vomiting. Do not give anything to an unconscious person. CALL A PHYSICIAN CONTACT A POISON CONTROL CENTER SECTION 4: HAZARDOUS INGREDIENTS _____ HAZARD DATA CARCINOGEN ACGIH OSHA NAME/CAS # 8 IARC NTP OSHA TLV PEL _____ This section is not applicable to the products: Bacitracin-neomyxin-polymyxin topical ointment and sterile ophthalmic ointment SECTION 5: FIRE AND EXPLOSION HAZARD DATA _____ FLASH POINT (Closed Cup): 390 deg F, 199 deg C (97% Petrolatum concentration) AUTO-IGNITION TEMPERATURE deg. F: Not determined FLAMMABLE LIMITS IN AIR BY VOLUME: Not determined LEL: Not determined UEL: Not determined EXTINGUISHING MEDIA: Alcohol foam, dry chemical and CO2. SPECIAL FIRE FIGHTING PROCEDURES: Wear full protective clothing. UNUSUAL FIRE AND EXPLOSION HAZARDS: May emit toxic fumes.

_____ SECTION 6: REACTIVITY DATA (PHYSICAL HAZARDS) _____ STABILITY: Stable INCOMPATIBILITY (Material to Avoid): Extreme heat, sparks, open flame, oxidizers, strong acids and alkalies. HAZARDOUS DECOMPOSITION PRODUCTS: May give off fumes of carbon monoxide and carbon dioxide. HAZARDOUS POLYMERIZATION: Should not occur -----SECTION 7: HEALTH HAZARDS _____ PRIMARY ROUTE(S) OF ENTRY: Dermal SIGNS AND SYMPTOMS OF EXPOSURE (For animal effects see package insert.): A. OVEREXPOSURE EFFECTS: Allergy, kidney and liver impairment, dizziness, incoordination, sensory loss, deafness, nausea, vomiting and diarrhea. B. CHRONIC EFFECTS: May cause allergic reactions in susceptible individuals. 1. INHALATION: Not likely due to physical state of the product. 2. EYES: Use only specified ophthalic ointment in eyes. Topical ointment will cause eye irritation. 3. SKIN: Non-toxic under standard application. 4. INGESTION: May cause kidney, liver and gastro-intestinal impairment; may induce dizziness, incoordination, sensory loss and deafness. 5. MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY: Susceptible individual may have an allergic reaction. _ _ _ SECTION 8: SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES _____ PRECAUTIONS TO BE TAKEN IN HANDLING/STORAGE: Keep containers 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. Add sand or dirt. Scoop up and remove. Dispose 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 9: SPECIAL PROTECTION INFORMATION _____ RESPIRATORY PROTECTION: General ventilation. SKIN PROTECTION: Normal hygiene. EYE PROTECTION: Normal hygiene. OTHER PROTECTIVE CLOTHING OR EQUIPMENT: As needed to prevent repeated prolonged contact. _____ _____ SECTION 10: CONTAINERS AND LABELING _____ SPECIAL PRECAUTIONS: Keep container closed. Store away from oxidizers and sources of heat and flame. RECOMMENDED CONTAINER: As supplied (not sold in bulk quantity). PROTECT THE CONTAINER BY: Avoiding physical damage and heat.

CONTAINER SHOULD BE HANDLED IN AN AREA WITH: Cool dry conditions.

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BACITRACIN-NEOMYCIN-POLYMYXIN STERILE OPHTHALMIC OINTMENT

THE EMPTY CONTAINER IS: Not reusable PRECAUTIONARY LABEL: No WARNING PLACARD: No IMO HAZARD CLASS#: Not applicable UN/NA#: Not applicable HAZARD CLASSIFICATION: Not applicable DOT NAME: Not applicable SHIPPING INSTRUCTIONS: Keep away from oxidizers and sources of heat. _____ SECTION 11: ENVIRONMENTAL RISKS _____ _____ AOUATIC TOXICITY: Not indicated BIODEGRADABILITY: Not indicated PARTITION COEFFICIENT: Not indicated _____ SECTION 12: REGULATORY INFORMATION REFER TO THE FOLLOWING REFERENCES: OSHA REGULATIONS: If respirator used, 29 CFR 1900.134 DOT REGULATIONS: Not applicable EPA REGULATIONS: Not applicable OTHER: 21 CFR 330.5 _____ SECTION 13: PHYSICAL DATA APPEARANCE AND ODOR: A pale, yellow ointment that is odorless. MOLECULAR WEIGHT: Not applicable pH: Not applicable REFRACTIVE INDEX @ 20 deg. C: Not indicated VISCOSITY CPS @ 25 deg. C: Not indicated BOILING POINT deg. F: 392 BOILING POINT deg. C: 200 FREEZING/MELTING POINT deg. F: 136 FREEZING POINT deg. C: 58 CONGEALING POINT deg. F: Not indicated CONGEALING POINT deg. C: Not indicated VAPOR PRESSURE (mmHg @ 20 deg. C): <1 mm VAPOR DENSITY (Air = 1): Not indicated SOLUBILITY IN WATER: Insoluble SOLUBILITY IN ALCOHOL: Practically insoluble SOLUBILITY IN OIL: Soluble SOLUBILITY IN OTHER: Most polar solvents SPECIFIC GRAVITY (H2O = 1): 0.85 @ 60 deg C % VOLATILE BY VOLUME: 0 EVAPORATION RATE: 0.00 (ether reference) _____ DATE OF PREPARATION/CHANGE: May 11, 1989 ------The information presented herein relates to the specific material described and may not be valid for this material used in combination with any other materials or in any process. This information is, to the best of our knowledge, accurate and reliable on the date compiled. We make no representation, warranty, or guarantee as to its accuracy, reliability or completeness. It is the reader's responsibility to ascertain whether the information supplied is suitable and complete for that person's specific uses. _____ DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES: Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s). A request has been made to the manufacturer to approve the contents of this material safety data sheet. Upon receipt a new MSDS will be made available. _____ COMPAS Code: 14060050