SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

PART I *What is the material and what do I need to know in an emergency?*

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME:	**MUPIROCIN OINTMENT**
CHEMICAL NAME:	Active Ingredient: (E)-(2S,3R,4R,5S)-5-[(2S,3S,4S,5S)-2,3-Epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy-β- methyl-2H-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid
CHEMICAL CLASS:	Active Ingredient: Heterocyclic Fatty Acid/Pyran
THERAPEUTIC CLASS:	Topical Antibiotic
OTHER MEANS OF IDENTIFICATION/SYNONYMS:	None
RELEVANT USE of the PRODUCT:	Human Pharmaceutical
USES ADVISED AGAINST:	Other than Relevant Use
HOW SUPPLIED:	20 mg in 1 g Clear Ointment: NDC:0093-1010-42: 22 g in 1 tube

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME:	**TEVA**
ADDRESS:	1090 Horsham Road North Wales, PA 19454
BUSINESS PHONE:	215-591-3000 [08:00 AM --> 05:00 PM]
EUROPEAN SUPPLIER/MANUFACTURER'S NAME:	**TEVA/TAPI**
ADDRESS:	Sicor sri-Via Terrazzano 77-20017 Cho (MI), Italy
BUSINESS PHONE:	+39 02 93197 306 [08:00 AM --> 05:00 PM]
EMERGENCY PHONE:	United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs] International: 01-703-527-3887 (Chemtrec) [24-hours]
EMAIL:	TevaSDSRequest@tevapharm.com
DATE OF PREPARATION:	March 4, 2014
DATE OF REVISION:	New

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: Product Description: This product is a colorless to pale yellow ointment with a mild odor. **Health Hazards:** In the workplace, exposure via inhalation or eye contact may cause irritation. Prolonged skin contact may cause redness or skin discomfort. Ingestion may be harmful. In therapeutic use, the most common adverse effects reported included rash, nausea, reddening of skin, dry skin, tenderness, swelling, contact dermatitis, and increased pus (when present). Prolonged therapeutic use may cause an overgrowth of non-susceptible organisms, including fungi. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for information on other potential health hazards known from therapeutic use. **Flammability Hazards:** This product is combustible and may ignite if exposed to direct flame or if highly heated for a prolonged period. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds, including carbon and nitrogen oxides, ethylene glycol, formaldehyde, formic acid, glyoxal, and dioxalane. **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.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	LABEL ELEMENTS EU Classification (67/548/EEC) GHS and EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Mupirocin (E)-(2S,3R,4R,5S)-5-[(2S,3S,4S,5S)-2,3-Epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy-β- methyl-2H-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid	12650-69-0	Not Listed	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: None applicable. Risk Phrase Codes: None applicable. Hazard Symbols: None applicable. GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: None applicable.
EXCIPIENTS				
Polyethylene Glycols 400 and 3350	25322-68-3	NLP # 500-038-2	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable

See Section 16 for full classification information of product and components.

PART II *What should I do if a hazardous situation occurs?*

4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

Skin Exposure: If skin contact with this product occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

Eye Exposure: If this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

Inhalation: If aerosols of this product are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. 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 emergency medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing renal insufficiency may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to this material, or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available for product. For Polyethylene Glycol: 227°C (441°F) (closed cup)

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

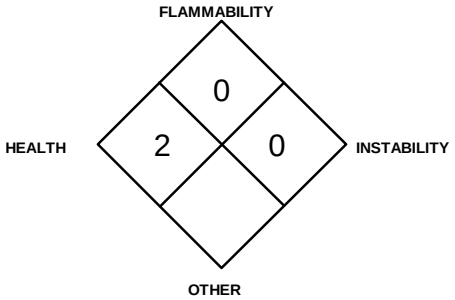
SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product is not flammable. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides, ethylene glycol, formaldehyde, formic acid, glyoxal, and dioxalane).

Explosion Sensitivity to Mechanical Impact: Not applicable.

Explosion Sensitivity to Static Discharge: Not applicable.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinse before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows, a small scoop to collect glass fragments (if applicable) and two large waste disposal bags. Absorbents should be able to be incinerated. Spills may be slippery and present slip hazard. Avoid generating aerosols of this product during spill response procedures as described below.

PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection should immediately clean spills of less than 5 mL.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, and protective clothing (i.e., disposable Tyvek coveralls). When there is any danger of airborne aerosols being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: The spilled product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Spills in Hoods: Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated, label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.

Large Spills: Restrict access to the spill areas. For spills of greater than 5 mL, limit spread by gently covering with absorbent sheets, spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11, & 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this product is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this product. Minimize all exposures to product. Avoid generation of aerosols. Areas in which this product is used should be wiped down, so that product does not accumulate.

CONDITIONS FOR SAFE STORAGE: Containers of product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F). Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat or suitable protective clothing. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

Workplace Exposure Limits/Control Parameters:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	ppm
Mupirocin	12650-69-0	NE	NE	NE	NE	NE	NE	NE	**Teva OEL Range µg/m^3 ≥ 100 - < 3000** (established 05Mar2012)
Propylene Glycol 440 and 3350	25322-68-3	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

International Occupational Exposure Limits: Exposure limits available for some excipient components are given below.

POLYETHYLENE GLYCOL PEG 400:
Denmark: TWA = 1000 mg/m^3, MAY 2011
Germany: MAK = 1000 mg/m^3 (inhalable), 2005
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003

POLYETHYLENE GLYCOL 3350:
Denmark: TWA = 1000 mg/m^3, OCT 2002
Germany: MAK = 1000 mg/m^3 (inhalable), 2005
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003
Russia: STEL = 10 mg/m^3, JUN 2003

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132)*, equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. 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 U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

Skin Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the formulated product:

FORM: Somewhat viscous ointment.
COLOR: Clear to pale yellow.
ODOR: Mild odor.
ODOR THRESHOLD: Not available.
FLASH POINT: For Polyethylene Glycol: 227°C (441°F) (closed cup)
SPECIFIC GRAVITY: Not available.
BOILING POINT: Not available.
pH: Not available.
SOLUBILITY IN WATER: Miscible.
OTHER SOLUBILITIES: For Polyethylene Glycol: Soluble in all proportions in many organic solvents (e.g., acetone, n-butyl acetate, glycerin, methanol, ethanol, n-propanol, 1,4-dioxane, nitromethane, and benzene). Very soluble in xylene and ethylbenzene; soluble in diethylbenzene, isopropylbenzene, and carbon tetrachloride. Insoluble in cyclohexane, triethylbenzene, and other hydrocarbons.
HOW TO DETECT THIS SUBSTANCE (identification properties): The ointment appearance of this product may be a good method to identify it in event of an accidental release.

The following values are for the active ingredient, Mupirocin:

FORM: Crystalline solid.
COLOR: White to off-white.
MOLECULAR WEIGHT: 500.63
MOLECULAR FORMULA: $C_{26}H_{44}O_9$
ODOR: Not available.
ODOR THRESHOLD: Not available.
BOILING POINT @ 760 mmHg: 672.3±55.0°C (1242.14±131°F) [predict.]
pH: Not available.
VAPOR PRESSURE (air = 1) @ 25°C: 0.0±4.7 mmHg [predict.]
EVAPORATION RATE (nBuAc = 1): Not applicable.
SPECIFIC GRAVITY (water = 1): 1.2±0.1 g/cm^3 [predict.]
MELTING POINT: 77-78°C (170.6-172.4°F)
FLASH POINT: 216.5±25.0°C (412.7±77°F) [predict.]
SOLUBILITY IN WATER: 2.65e-02 mg/mL [predict.]
COEFFICIENT WATER/OIL DISTRIBUTION: Log P: 3.44±0.48 [predict.]
OTHER SOLUBILITIES: Not available.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Normally stable. Due to high Propylene Glycol content, product may oxidize slowly on prolonged contact with air to form peroxides unless stabilizers are present. Can decompose upon exposure to light.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon and nitrogen oxides, ethylene glycol, formaldehyde, formic acid, glyoxal, and dioxalane. *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with oxidizing agents.

10. STABILITY and REACTIVITY (continued)

POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: None known.
CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

PART IV *Is there any other useful information about this product?*

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The main route of occupational exposure to this product is via skin contact and accidental eye contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

Inhalation: Inhalation of the product is unlikely due to ointment form. If aerosols are somehow generated and inhaled, irritation of the nose and upper respiratory system may occur. Symptoms of such exposure may include sneezing, coughing, and nasal congestion.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness and other symptoms described under 'Other Health Effects'. Symptoms of eye contact may include redness, pain, and watering.

Skin Absorption: This product is designed to be absorbed into the skin.

Ingestion: Ingestion of this product is not anticipated to be a significant route of occupational exposure. Ingestion of this product (i.e., through poor hygiene practices) may irritate the mouth, throat, and other tissues of the gastrointestinal system. No specific information is available on symptoms of acute ingestion.

Injection: Accidental injection of this product, via laceration or puncture by a contaminated object may cause pain and irritation in addition to the wound.

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use the most common adverse effects reported included rash, nausea, reddening of skin, dry skin, tenderness, swelling, contact dermatitis, and increased pus (when present). Prolonged therapeutic use may cause an overgrowth of non-susceptible organisms, including fungi.

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: This product may cause irritation via inhalation or skin or eye contact. Ingestion may be harmful.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause symptoms as described under 'Other Potential Health Effects'.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	1
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

TARGET ORGANS: Acute: Occupational Exposure and Therapeutic Use: Skin, eyes. Chronic: Occupational Exposure: Skin. Therapeutic Use: See information under 'Other Health Effects'.

TOXICITY DATA: Currently, the following toxicological data are available for this the active ingredient of this product. Data are available for excipient components, but are not presented in this SDS. Contact Teva for information on toxicity data for excipients.

MUPIROCIN:
LD_{50} (Oral-Rat) 5 gm/kg
LD_{50} (Oral-Mouse) 5 gm/kg
LD_{50} (Subcutaneous-Rat) 5 gm/kg

MUPIROCIN (continued):
LD_{50} (Subcutaneous-Mouse) 4 gm/kg
LD_{50} (Intravenous-Rat) 1310 mg/kg
LD_{50} (Intravenous-Mouse) 1638 mg/kg

CARCINOGENIC POTENTIAL OF COMPONENTS: The following information is for the active ingredient.

The carcinogenic potential of Mupirocin has not been evaluated.

The remaining component of this product is not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product may cause eye or respiratory system irritation. Prolonged skin contact may be irritating.

SENSITIZATION TO THE PRODUCT OR ITS COMPONENTS: No specific information available.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Mupirocin in pregnant women; however, when administered therapeutically, Mupirocin is not expected to cause fetal harm when administered to a pregnant woman. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category B. Refer to Definition of Terms for full Pregnancy Risk category definitions.

Mutagenicity: Results of the following studies performed with mupirocin calcium or mupirocin sodium *in vitro* and *in vivo* did not indicate a potential for genotoxicity: rat primary hepatocyte unscheduled DNA synthesis, sediment analysis for DNA strand breaks, Salmonella reversion test (Ames), *Escherichia coli* mutation assay, metaphase analysis of human lymphocytes, mouse lymphoma assay, and bone marrow micronuclei assay in mice.

Embryotoxicity/Teratogenicity: Reproduction studies have been performed in rats and rabbits with Mupirocin administered subcutaneously at doses up to 22 and 43 times, respectively, the human topical dose (approximately 60 mg mupirocin per day) on a mg/m^2 basis and revealed no evidence of harm to the fetus due to Mupirocin.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Reproductive Toxicity: Reproduction studies were performed in male and female rats with mupirocin administered subcutaneously at doses up to 14 times a human topical dose (approximately 60 mg mupirocin per day) on a mg/m^2 basis and revealed no evidence of impaired fertility and reproductive performance from Mupirocin. It is not known whether this drug is excreted in human milk. Because there is potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: Currently, there is no specific information available on the potential mobility of this product.

PERSISTENCE AND BIODEGRADABILITY: Currently, there is no specific information on persistence and biodegradability of this product. Some biodegradation is expected.

BIO-ACCUMULATION POTENTIAL: Currently, no specific information is available on the bioconcentration potential of this product.

ECOTOXICITY: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No toxicological data are available.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: The components of this product are not listed as having ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, 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. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

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

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and components are not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. 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.

U.S. SARA Threshold Planning Quantity: There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

U.S. CERCLA Reportable Quantity (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

Other U.S. Federal Regulations: Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component is on the California Proposition 65 Lists.

State Regulations: Regulated Medical Waste.

ADDITIONAL CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: This product is regulated by the Therapeutic Products Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

Canadian Environmental Protection Act (CEPA) Priority Substances Lists: Components are not on the CEPA substances lists.

Other Canadian Regulations: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

Canadian WHMIS Classification and Symbols: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

ADDITIONAL EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **CAUTION!** MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. MAY BE HARMFUL IF SWALLOWED. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Wear gloves, goggles, and suitable body protection. **FIRST-AID:** If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. If alert, give victim up to three glasses of water. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. **IN CASE OF FIRE:** Use water fog, dry chemical or CO_2, or alcohol foam. **IN CASE OF SPILL:** Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008:

Mupirocin: The following is a Self-Classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statement Codes: H303: May be harmful if swallowed.

All Other Components: No classification has been published or is applicable.

FULL TEXT EU 67/548/EEC:

All Components: No classification has been published or is applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

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