1. SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

<table>
<thead>
<tr>
<th>TRADE NAME/MATERIAL NAME: Bacitracin Zinc Ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION: Bacitracin Zinc Ointment</td>
</tr>
<tr>
<td>NDC #: 0168-0011-04; 0168-0111-09; 0168-0011-16; 0168-0011-31; 0168-0011-35</td>
</tr>
<tr>
<td>CHEMICAL NAME (for active ingredient): (2R,3S,4R,5R,6R)-5-amino-2-(aminomethyl)-6-{[(1R,2R,3S,4R,6S)-4,6-diamino-2-({2S,3S,4S,5R}-4-[(2R,3S,4S,5S,6S)-3-amino-6-(aminomethyl)-4,5-dihydroxoyxan-2-yl}]oxy}-3-amino-6-(aminomethyl)-4,5-dihydroxoyxan-2-yl}]oxy}-3-hydroxy-5-(hydroxymethyl)oxolan-2-yl}]oxy}-3-hydroxyaclohexy}]oxy}oxane-3-3-hydroxyclohexy}]oxy}oxane-3,4-diol</td>
</tr>
<tr>
<td>CHEMICAL FAMILY: Cyclic Polypeptide</td>
</tr>
<tr>
<td>HOW SUPPLIED: Bacitracin Zinc Topical Ointment</td>
</tr>
<tr>
<td>FORMULA (for active ingredient): C_{68}H_{107}N_{17}O_{16}S_{2}Zn</td>
</tr>
<tr>
<td>RELEVANT USE of the SUBSTANCE: Pharmaceutical for Human Use</td>
</tr>
<tr>
<td>USES ADVISED AGAINST: Other than Relevant Use</td>
</tr>
<tr>
<td>SUPPLIER/MANUFACTURER’S NAME: FOUGERA PHARMACEUTICALS INC.</td>
</tr>
<tr>
<td>ADDRESS: 60 Baylis Road</td>
</tr>
<tr>
<td>Melville, NY 11747</td>
</tr>
<tr>
<td>BUSINESS PHONE/GENERAL SDS INFORMATION: 1-631-454-7677</td>
</tr>
<tr>
<td>EMERGENCY PHONE (U.S./Canada/Puerto Rico): CHEMTEL: (U.S., Canada) 1(800)255-3924 (24 hrs) (International) +1 813 248 0585 (24 hrs)</td>
</tr>
<tr>
<td>EMERGENCY PHONE (OUTSIDE U.S.): 01-631-454-7677</td>
</tr>
</tbody>
</table>

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.


EMERGENCY OVERVIEW: Product Description: This product is a pale yellow ointment with a petroleum jelly odor. Health Hazards: May be harmful if swallowed. Prolonged skin contact may be irritating. Individuals who have had allergic reactions to aminoglycosides may experience allergic reactions to this product, including skin and respiratory sensitization and allergic reactions. Therapeutic use of this product may cause adverse symptoms on the neurological system, ears, liver and kidneys. Flammability Hazards: If heated to high temperatures for a prolonged period, this product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen, zinc and sulfur oxides). Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects; however, all release to the environment should be avoided. The active ingredient may cause acute and chronic toxicity to aquatic organisms. Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>LABEL ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-89-6</td>
<td>215-787-8</td>
<td>500 Units</td>
<td>SELF-CLASSIFICATION</td>
</tr>
<tr>
<td>L-isoleucinamide, N-[(2-[1-amino-2-methylbutyl]-4,5-dihydro-4-thiazolyl] carbonyl] L-leucyl-D--glutaryl-N-[(3S,6R,9S,12S,15S,17S,21S)-3-[2-amino-2-oxoethyl]-18-(3-aminopropyl)-6- (carboxymethyl)-9-[1-(imidazol-5-ethyl)]-15- (1-methylpropyl)-2,5,8,11,14,17,20-heptaoxo-12- (phenylmethyl)-1,4,7,10,13,16,19- heptaazacyclopentacos-21-yl]-, zinc salt (1:1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

See Section 16 for full classification information of product and components.
### 3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>LABEL ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EU Classification (67/548/EEC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>GHS &amp; EU Classification (1272/2008 EC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Risk Phrases/Hazard Statements</td>
</tr>
</tbody>
</table>

**EXCIPIENTS**

| White Petrolatum | 8009-03-8 | 232-373-2 | Proprietary | EU 67/548  
Classification: Carcinogenic Cat. 2  
Risk Phrase Codes: R45  
Hazard Symbols: Xn  
GHS and EU 1272/2008  
Classification: Carcinogenic Cat. 1B  
Hazard Codes: H350  
Hazard Symbol/Pictogram: GHS08 |

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

**PROTECTION OF FIRST AID RESPONDERS:** rescuers should wear adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

**DESCRIPTION OF FIRST AID MEASURES:** Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s).

**Skin Exposure:** If adverse skin effects occur, discontinue use. Seek medical attention.

**Eye Exposure:** If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

**Inhalation:** If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

**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.

**IMPORTANT SYMPTOMS AND EFFECTS:** See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** Pre-existing liver and kidney conditions and hearing problems and may be aggravated by exposure to this product. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to aminoglycosides or the components, and 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. No specific antidote is known. Treatment should be symptomatic and supportive.

### 5. FIRE-FIGHTING MEASURES

**FLASH POINT:** Not available.

**AUTOIGNITION TEMPERATURE:** Not available.

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

**FIRE EXTINGUISHING MEDIA:** Use extinguishing media appropriate for surrounding fire.

**UNSUITABLE FIRE EXTINGUISHING MEDIA:** None known.

**SPECIAL HAZARDS ARISING FROM THE PRODUCT:** If heated to high temperatures for a prolonged period this product can ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, nitrogen, zinc and sulfur oxides).

**Explosion Sensitivity to Mechanical Impact or Static Discharge:** Not sensitive.

**SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS:** 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 running 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

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 and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product. Spills may be slippery.

PROTECTIVE EQUIPMENT:
Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.
Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, full body gown, and 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:
Small Spills: The 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.
Large Spills: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 mL, limit spread by gently covering with absorbent sheets, or 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 allow 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 product 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 and 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 USE

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. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

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

CONDITIONS FOR SAFE STORAGE: Containers of this 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) [USP Controlled Room Temperature]. Protect from freezing. 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. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). 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. Wipe equipment down with damp sponge or polypad. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Collect all rinsates and dispose of according to applicable waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

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 SDS.

Workplace Exposure Limits/Control Parameters:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ACGIH TLVs</td>
</tr>
<tr>
<td></td>
<td>mg/m³</td>
<td>mg/m³</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-89-6</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established See Section 16 for Definitions of Terms Used.

BACITRACIN ZINC OINTMENT SDS PAGE 3 OF 10 EFFECTIVE DATE: MAY 30, 2015
8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
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<th>EXPOSURE LIMITS IN AIR</th>
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<tbody>
<tr>
<td></td>
<td>ACGIH-TLVs</td>
<td>OSHA-PELs</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-89-6</td>
<td>NE</td>
</tr>
<tr>
<td>White Petroleum</td>
<td>8009-03-8</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established  See Section 16 for Definitions of Terms Used.

International Occupational Exposure Limits: No additional international exposure limits are available for components. Exposure limits are added or changed and should be check periodically.


Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. 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.

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.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial 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.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Ointment.
COLOR: Pale yellow.

MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.

ODOR: Petroleum jelly odor.
ODOR THRESHOLD: Not established.

BOILING POINT: > 200°C (392°F)
MELTING POINT: Approx. 58°C (136°F)

EVAPORATION RATE (nBuAc = 1): 0
pH: Not established.

VAPOR PRESSURE (air = 1): < 1 mmHg
SPECIFIC GRAVITY (water = 1): 0.85

SOLUBILITY IN WATER: Insoluble.
OTHER SOLUBILITIES: Not known.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon, nitrogen, zinc and sulfur oxides). Hydrolysis: None known.

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.

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

PART IV Is there any other useful information about this material?

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Although unlikely, due to high viscosity of the product, inhalation of mists or sprays of this product, especially in a poorly ventilated space, may cause irritation, coughing, and sneezing.

Contact with Skin or Eyes: Skin contact may cause burning sensation, stinging, prickling, itching, and tingling.
11. TOXICOLOGICAL INFORMATION (Continued)

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE (continued):

Contact with Skin or Eyes (continued): Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals. Eye contact can cause temporary blurred vision and irritation.

Skin Absorption: This product can be absorbed through open wounds, burns, and granulating surfaces. Absorption can be significant and can adversely affect the kidneys and destroy fibers of the acoustic nerve and cause permanent bilateral deafness. When absorbed Polymyxin B is a nephrotoxic antibiotic (can cause damage to the liver), and the nephrotoxic potentials are additive.

Ingestion: Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause nausea, vomiting, diarrhea and inflammation of the small intestine and the colon. Although ingestion may cause severe allergic reactions, reactions are rare. Chronic ingestion caused by poor hygiene practices may cause weight loss, diarrhea, excess fat in the stools, excessive discharge of nitrogenous substances in the feces or urine, difficulty digesting dairy products, intestinal crypt-cell necrosis, kidney damage, hearing loss, and hair loss.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms of intramuscular injection of Bacitracin Zinc may include loss of appetite, nausea, vomiting, diarrhea, rectal itching and burning, skin rashes, pain, hives, fever, bone marrow toxicities, blood dyscrasias, eosinophilia, kidney damage, and anaphylactoid reactions. Reaction may be life-threatening in certain individuals.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, damage to the kidneys, liver or renal damage, ototoxicity (damage to hearing) and neuromuscular blockage have been reported. Hypersensitivity to aminoglycosides may cause rash. Ingestion can cause serious allergic reactions in susceptible individuals. Allergic reaction by inhalation may be possible. Increased liver toxicity has been reported following concurrent administration of aminoglycosides and cephalosporins. Acute muscular paralysis and breathing disorders due to this can occur with aminoglycoside drugs. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.

IRRITATION OF PRODUCT: This product may irritate contaminated tissue if contact is prolonged.

SENSITIZATION OF PRODUCT: Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Bacitracin is considered to be one of the most prevalent allergens. Rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals.

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

Acute: Ingestion may be harmful. Eye contact may cause irritation.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. May cause fetal harm. Chronic exposure to this material may cause adverse effects as described under ‘General Toxicity Information’.

TARGET ORGANS:

Acute: Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin.

Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin, other effects described under ‘Other Potential Health Effects’.

TOXICITY DATA: Currently, no toxicity data available for the active component of this product. Additional data are available for the excipient components of this product, but are not presented; Contact Fougera for more information.

CARCINOGENIC INFORMATION: No information is available for of the active ingredients. The remaining components of this product are 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.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of in pregnant women. This product has not been rated by the U.S. FDA for Pregnancy Risk Category.

Mutagenicity: Long- term studies in animals to evaluate or mutagenic potential have not been conducted with Polymyxin B Sulfate.

Embryotoxicity/Teratogenicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and there have been several reports of total irreversable, bilateral congenital deafness in children whose mothers received streptomycin (a related aminoglycoside) during pregnancy. Although serious side effects to the fetus or newborns have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists.
11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Reproductive Toxicity: Some aminoglycosides have been shown to be excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIOACCUMULATION: This product has not been tested for bioconcentration.

ECOTOXICITY: 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 terrestrial and aquatic plant and animal life, especially in large quantities. The following data are available for one active component.

**BACITRACIN ZINC:**

LC\textsubscript{50} (Trout) 96 hours = 74 mg/L

EC\textsubscript{50} (Artemia sp. Brine shrimp) 48 hours = 18,500 to 25,700 µg/L (21.82 mg/L)

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.

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

OTHER ADVERSE EFFECTS: No component of this product is known to have ozone depletion potential.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: 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 of. 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. Shipment of wastes must be done with appropriately permitted and registered transporters.

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.

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. 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 product 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.

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 SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as 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 is not specifically listed in Annex III under MARPOL 73/78.
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.
U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS 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 by the Food and Drug Administration; it is not subject to requirements under TSCA.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component is listed on the California Proposition 65 lists.
Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations. 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.
CANADIAN REGULATIONS:
Canadian DSL/NDSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.
Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: No component is on the CEPA Priorities Substances List.
Other Canadian Regulations: Not 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.
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.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! MAY HARMFUL IF ACCIDENTALLY INGESTED. PROLONGED THERAPEUTIC USE MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE ALLERGIC SKIN AND RESPIRATORY REACTIONS. CONTAINS TRACE COMPOUND THAT MAY CAUSE ACUTE AND CHRONIC HARM TO AQUATIC ORGANISMS. Do not taste or swallow. Avoid contact with skin or clothing. Avoid breathing mists or sprays. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, call a physician immediately. Do NOT induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO₂, or “alcohol” foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet 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 exempted from classification and other criteria of 1272/2008.
CLASSIFICATION FOR COMPONENTS:
Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:
Bacitracin Zinc: This is a self-classification.
Classification: Skin Sensitization Category 1B, Aquatic Acute Toxicity Category 3, Aquatic Chronic Toxicity Category 3
White Petrolatum: The following is a Self-Classification.
Classification: Carcinogenic Category 1B
Hazard Statements: H350: May cause cancer.
All Other Components: No classification has been published or is applicable.
CLASSIFICATION FOR COMPONENTS (continued):

**Full Text EU 67/548/EEC:**

**Bacitracin Zinc:** This is a self-classification.

*Classification:* Irritant, Dangerous for the Environment

*Risk Phrases:* R43: May cause sensitisation by skin contact. R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**White Petrolatum:** The following is a Self-Classification.

*Classification:* Carcinogenicity Category 2

*Risk Phrases:* R45: May cause cancer.

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

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DEFINITION OF TERMS

A large number of abbreviations and acronyms appear on a SDS. 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 work exposure.

**TWA:** Time Weighted Average — The exposure that shall not be exceeded during any part of the workday. It is the weighted average of the concentration that would be expected if the worker were continuously exposed throughout the workday to a concentration of the substance that does not exceed the ceiling level and to concentrations of other substances in combination that do not exceed the ceiling level. The TWA is based on an 8-hour period.

**PEL:** Permissible Exposure Limit. This exposure value means exactly the same thing as the TWA. PEL was vacated by the OSHA in the year 1989. The phrase, “Vacated 1989 PEL” is placed next to this exposure value.

**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.

**LOG:** Logarithm of Quotient.

**MAK:** MAK stands for “Maximum Arbeitsplatz Konzentrationen,” the term that is used in Germany for MAK values. They are time-weighted average daily concentrations, calculated on the basis of an 8-hour working day. MAK values are expressed in milligrams per cubic meter (mg/m³).

**NIOSH:** The National Institute for Occupational Safety and Health, the federal agency in the U.S. that deals with workplace safety and health issues.

**NIOSH RELs:** NIOSH recommends Exposure Limits. This exposure value means exactly the same thing as the MAK.

**PEL:** Permissible Exposure Limit. This exposure value means exactly the same thing as the TWA. PEL was vacated by the OSHA in the year 1989. The phrase, “Vacated 1989 PEL” is placed next to this exposure value.

**REVISION DETAILS:** May 2015: Review and up-date SDS to comply with EU CLP and the Global Harmonization Standard. Correction of CAS# for Bacitracin Zinc in Sections 3 and 8.

**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.

**PREPARED BY:** CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

**DATE OF PRINTING:** June 27, 2015

**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. Mechanical irritation may occur. Pll or Draize = 0. Eye Irritation: Essentially non-irritating. Minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. Oral Toxicity LD₅₀ Rat or Rabbit > 5000 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit > 2000 mg/kg. Inhalation Toxicity 4-hrs LC₅₀ Rat or Rabbit > 20 mg/L.
- **1 Slight Hazard:** Minor reversible injury may occur; may irritate the stomach if swallowed; may damage the skin and exacerbate existing dermatitis. Skin Irritation: Slightly or mildly irritating. PII or Draize > 0 < 5. Eye Irritation: Slightly to mildly irritating but reversible within 7 days. Draize > 5 ≤ 25. Oral Toxicity LD₅₀ Rat or Rabbit > 500–5000 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit > 100–2000 mg/kg. Inhalation Toxicity LC₅₀ Rat or Rabbit > 2–20 mg/L.
- **2 Moderate Hazard:** Temporary or transitory injury may occur; prolonged exposure may affect the CNS. Skin Irritation: Moderately irritating; primary irritant; sensitizer. PII or Draize > 5. With no destruction of dermal tissue. Eye Irritation: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. Oral Toxicity LD₅₀ Rat or Rabbit > 50–500 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit > 200–1000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat > 0.5–2 mg/L.
- **3 Serious Hazard:** Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. Skin Irritation: Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dental necrosis. PII or Draize > 5–8, with destruction of tissue. Eye Irritation: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. Oral Toxicity LD₅₀ Rat or Rabbit > 1–50 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit > 20–200 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat > 0.05–0.5 mg/L.
- **4 Severe Hazard:** Life-threatening; major or permanent damage may result from single or repeated exposure; extremely toxic; irreversible injury may result from brief contact. Skin Irritation: Not appropriate. Do not rate as a 4, based on skin irritation alone. Eye Irritation: Corrosive, irreversible destruction of eye tissue including full thickness of cornea with possibly full thickness of iris. Inhalation Toxicity 50% Mortality Time to Death LD₅₀ Rat > 4 hrs. LD₅₀ Rat ≥ 1 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit ≥ 20 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat ≤ 0.05 mg/L.

**Hazardous Substance:**

- **0 Minimal Hazard:** Materials that will not burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes. 1 Slight Hazard: Materials that must be pre-heated before ignition can occur. Material requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class II); and Most ordinary combustible materials (e.g. wood, paper, etc.). 2 Moderate Hazard: Materials that must be moderately heated or exposed to relatively high ambient temperature before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres with air. This usually includes the following: Liquids having a flash-point at or above 37.8°C (100°F); Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); and Solids and semisolids (e.g. viscous and slow flowing as asphalt) that readily give off flammable vapors. 3 Serious Hazard: Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions. This usually includes the following: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. OSHA Class IIIA and B); and Most ordinary combustible materials (e.g. wood, paper, etc.). 4 Severe Hazard: Materials that will burn in air when exposed to temperatures over 37.8°C (100°F) under any conditions; Materials that will burn in air when heated before ignition can occur; those materials that are ignited and self-sustaining; and those materials that, when heated in air, release vapor in sufficient quantities to produce a highly hazardous atmosphere with air. This usually includes the following: Materials having a flash point below 93.3°C (200°F); Solids that are easily ignited and burn rapidly with a high rate of combustion; Solid materials in the form of course dusts that may burn rapidly and produce an atmospheric or partial atmospheric explosion; Semisolids having a flash point below 93.3°C (200°F) and a boiling point at or above 38°C (100°F); and most ordinary combustible materials (e.g. wood, paper, etc.).

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**Effective Date:** May 30, 2015

**Bacitracin Zine Ointment SDS**
DEFINITION OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 4 Severe Hazard: Materials that will rapidly or completely vaporize at or above 100°C (212°F) that cause significant heat generation or explosion.

Oxidizers: Materials that contain greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

Unstable Reactives: Materials that, under emergency conditions, would offer no hazard for acute inhalation toxicity if its LC50 is greater than 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than 10 mg/L. Any liquid whose LC50 is greater than 0.5 mg/L but less than or equal to 2 mg/L.

Pyrophorics: Materials that, under emergency conditions, cause temporary incapacitation or residual injury.

Materials that will rapidly or completely vaporize in air and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) and Materials that have an LC50 in this degree requiring considerable heat or confinement before ignition and combustion can occur. Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lacrimators. Materials that are primary skin irritants or sensitizers. Materials whose LD50 for acute oral toxicity is greater than 1000 mg/kg but less than or equal to 5000 mg/kg and Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC50 for acute inhalation toxicity greater than 100,000 ppm but less than or equal to 1,000,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is greater than 100 mg/L. Any liquid whose LC50 is greater than 0.5 mg/L but less than or equal to 2 mg/L.

Oxidizers: Materials that must be heated under high temperatures and pressures. These materials may react with water, but will not release energy violently. Explosives: Division 1.5 & 1.6. Materials that may explode under certain conditions, but that do not cause a mass explosion hazard. Compounds containing greater than 0.5% by weight of a flammable or combustible solvent are not rated. Any solid that, under emergency conditions, would offer no hazard for acute inhalation toxicity if its LC50 is greater than or equal to 0.5 mg/L but less than or equal to 2 mg/L.

Pyrophorics: Materials that will rapidly or completely vaporize in air and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) and Materials that have an LC50 in this degree requiring considerable heat or confinement before ignition and combustion can occur. Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lacrimators. Materials that are primary skin irritants or sensitizers. Materials whose LD50 for acute oral toxicity is greater than 1000 mg/kg but less than or equal to 5000 mg/kg and Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC50 for acute inhalation toxicity greater than 100,000 ppm but less than or equal to 1,000,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is greater than 100 mg/L. Any liquid whose LC50 is greater than 0.5 mg/L but less than or equal to 2 mg/L.
DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD (continued): 3 Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. 4 Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). Flash Point: Minimum temperature at which a liquid gives off sufficient vapor to form an ignitable mixture with air near the surface of the liquid or within the test vessel used. Autoignition Temperature: Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition. LEL: Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. UEL: Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame.

TOXICOCLOGICAL 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. LD<sub>50</sub>: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC<sub>50</sub>: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/L: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose (or concentration) to cause a symptom. TCLo: Lowest concentration to cause a symptom. TD8, LDL8, and L8: or TC, TCo, LCo, and LCo: Lowest dose or concentration to cause lethal or toxic effects. Cancer Information: IARC: International Agency for Research on Cancer; NTP: National Toxicology Program; RTECS: Registry of Toxic Effects of Chemical Substances. 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.

REPRODUCTIVE TOXICITY INFORMATION:

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.

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. log K<sub>OC</sub> or log K<sub>OW</sub>: Coefficient of Oil/Water Distribution 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: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. WHMIS: Canadian Workplace Hazardous Materials Information System. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. DSL/NDSL: Canadian Domestic/Non-Domestic Substances List. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material’s package label.
### REVISION HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
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<tbody>
<tr>
<td>September 30, 2014</td>
<td>New</td>
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<tr>
<td>May 23, 2015</td>
<td>Review and up-date SDS to comply with EU CLP and the Global Harmonization Standard. Correction of CAS# for Bacitracin Zinc in Sections 3 and 8.</td>
</tr>
<tr>
<td>May 30, 2015</td>
<td>Change emergency telephone number to ChemTel.</td>
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</tbody>
</table>