MATERIAL SAFETY DATA SHEET
Prepared to U.S. OSHA, CMA, ANSI, and Canadian WHMIS

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

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Triple Antibiotic Ointment

DESCRIPTION: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate Ointment

NDC #: 0168-0012-09; 0168-0012-31; 0168-0012-35

CHEMICAL NAME (for active ingredient): Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate

CHEMICAL FAMILY (for active ingredient): Aminoglycoside Antibiotics

HOW SUPPLIED: Ointment

FORMULA (for active ingredient):

\[
\text{C}_{66}\text{H}_{103}\text{N}_{17}\text{O}_{16}\text{S/C}_{23}\text{H}_{46}\text{N}_{6}\text{O}_{13}\text{S/C}_{43}\text{H}_{82}\text{N}_{16}\text{O}_{12}\text{S} / \text{C}_{66}\text{H}_{103}\text{N}_{17}\text{O}_{16}\text{S} + \text{H}_{2}\text{O}_{4}\text{S}
\]

PRODUCT USE: Pharmaceutical for Human Use

SUPPLIER/MANUFACTURER’S NAME: NYCOMED US INC.

ADDRESS: 60 Baylis Road

Melville, NY 11747

BUSINESS PHONE/GENERAL MSDS INFORMATION: 1-631-454-7677

EMERGENCY PHONE (U.S./Canada/Puerto Rico): 1-800-424-9300 (24-hrs)

EMERGENCY PHONE (OUTSIDE U.S.): + 1-631-454-7677

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian WHMIS [Controlled Products Regulations] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Product Description: This product is a pale yellow ointment with a petroleum jelly odor. Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing Aminoglycosides or any other components of this product may experience allergic reactions to this product. Allergic reactions may be severe and can be life-threatening in certain individuals. Flammability Hazards: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and sulfur oxides). Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects; all release to the environment should be avoided. Emergency Considerations: Emergency responders should wear appropriate protection for situations to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-87-4</td>
<td>500 Units</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>0.4%</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>1405-20-5</td>
<td>10,000 Units</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

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

4 FIRST-AID MEASURES

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

SKIN EXPOSURE: 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 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.
4 FIRST-AID MEASURES (Continued)

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

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

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

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

5. FIRE-FIGHTING MEASURES

FLASH POINT (closed cup): 199°C (390°F)

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):
- Lower (LEL): Not applicable.  
- Upper (UEL): Not applicable.

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

FIRE EXTINGUISHING MATERIALS NOT TO BE USED: None known.

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, and sulfur oxides).


Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with 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

SPILL AND LEAK RESPONSE: Proper protective equipment should be used. In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA).

Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

Large Spills: Trained personnel following pre-planned procedures should handle non- incidental releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus. Absorb spilled liquid using polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Monitor area and confirm levels are bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).
Nycomed US Inc.

PART III How can I prevent hazardous situations from occurring?

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

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

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

SPECIFIC USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous 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

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

EXPOSURE LIMITS/GUIDELINES:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
<th>ACGIH-TLVs</th>
<th>OSHA-PELs</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>1405-87-4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
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</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Polymyxin B Sulfate</td>
<td>1405-20-5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

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

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) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07). Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA’s Respiratory Protection Standard (1910.134-1998).


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

BODY PROTECTION: During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee’s feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 and the Canadian CSA Standard Z195-02, Protective Footwear.

9. PHYSICAL and CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>property</th>
<th>value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOILING POINT</td>
<td>200°C (392°F)</td>
</tr>
<tr>
<td>EVAPORATION RATE (nBuAc = 1):</td>
<td>0</td>
</tr>
<tr>
<td>VAPOUR PRESSURE (air = 1):</td>
<td>&lt; 1 mm Hg</td>
</tr>
<tr>
<td>ODOR THRESHOLD:</td>
<td>Not established.</td>
</tr>
<tr>
<td>COEFFICIENT WATER/OIL DISTRIBUTION:</td>
<td>Not established.</td>
</tr>
<tr>
<td>pH</td>
<td>Not established.</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY @ 60°C (water = 1):</td>
<td>0.85</td>
</tr>
<tr>
<td>SOLUBILITY IN WATER:</td>
<td>Insoluble.</td>
</tr>
<tr>
<td>FREEZING/MELTING POINT:</td>
<td>58°C (136°F)</td>
</tr>
</tbody>
</table>

TRIPLE ANTIBIOTIC OINTMENT MSDS  EFFECTIVE DATE: MAY 04, 2009
9. PHYSICAL and CHEMICAL PROPERTIES (Continued)

APPEARANCE, ODOR AND COLOR: This product is a pale yellow ointment with a petroleum jelly odor.

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

STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: Combustion: Carbon oxides, nitrogen oxides, 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.

HAZARDOUS 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 OVEREXPOSURE 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 form of product, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. 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, anaphylactic shock, and cardiac arrest. Reaction may be life-threatening in certain individuals. Eye contact can cause temporary blurred vision and may cause corneal lesions.

SKIN ABSORPTION: Neomycin and Polymyxin B Sulfates 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.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product may cause nausea, vomiting, and diarrhea. 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.

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing Aminoglycosides or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following.

For Males and Females: Persons using the product in therapeutic doses may experience itching, swelling, and redness.

IRRITANCY OF PRODUCT: This product may mildly to moderately irritate contaminated tissue.
11. TOXICOLOGICAL INFORMATION (Continued)

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. Reaction may be life-threatening in certain individuals.

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

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Accidental ingestion may cause nausea, vomiting, and diarrhea. Eye contact can cause temporary blurred vision and may cause corneal lesions.

Chronic: 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, and hair loss.

TARGET ORGANS:

Acute: Occupational Exposure: Skin, eyes. Therapeutic Doses: Gastrointestinal system, kidneys, bone marrow.

Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin.

TOXICITY DATA: The toxicity data available for the active components of this product, Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate, are presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Nycomed US, Inc. for more information.

BACITRACIN ZINC:

**Acute:**
- LD₅₀ (Oral-Mouse) > 3750 mg/kg
- LD₅₀ (Oral-Guinea Pig) 2 gm/kg
- LD₅₀ (Oral-Dog) > 1000 mg/kg
- LD₅₀ (Intraperitoneal-Rat) 190 mg/kg: Lungs, Thorax, or Respiration: other changes
- LD₅₀ (Intrapleural-Mouse) 300 mg/kg
- LD₅₀ (Subcutaneous-Mouse) 1300 mg/kg:
  - Behavioral: somnolence (general depressed activity)
  - LD₅₀ (intravenous-Mouse) 360 mg/kg: Behavioral:
    - somnolence (general depressed activity), convulsions or effect on seizure threshold: Lungs, Thorax, or Respiration: other changes
- TCLo (Skin-Human) 20 pp/48 hours-continuous:
  - Skin and Appendages: dermatitis, allergic (after topical exposure)
  - DNA Adduct (Bacteria-Escherichia coli) 50 μmol/L

NEOMYCIN SULFATE:

- Standard Draize Test (Skin-Human) 6 mg/3 days-intermittent: Mild
- TDLo (Oral-Woman) 12.600 mg/kg/7 days:
  - Behavioral: somnolence (general depressed activity), hallucinations, distorted perceptions, anorexia (human)
- TCLo (Skin-Human) 20 pp/48 hours-continuous:
  - Skin and Appendages: dermatitis, allergic (after topical exposure)
- LD₅₀ (Oral-Mouse) > 8 gm/kg
- LD₅₀ (Subcutaneous-Rat) 200 mg/kg
- LD₅₀ (Subcutaneous-Mouse) 190 mg/kg

**NEOMYCIN SULFATE (continued):**

- LD₅₀ (Intraperitoneal-Mouse) 305 mg/kg
- LD₅₀ (Intravenous-Mouse) 17,400 μg/kg
- LD₅₀ (Intramuscular-Mouse) 142 mg/kg: Behavioral:
  - convulsions or effect on seizure threshold
  - LD₅₀ (Intramuscular-Guinea Pig) > 250 mg/kg: Ear:
    - change in acuity
  - LD₅₀ (Intracerebral-Mouse) 32 mg/kg
  - TDLo (Intraspinal-Rat) 36.88 μg/kg: Behavioral:
    - analgesia
  - TDLo (Intracerebral-Rat) 714.3 μg/kg: Blood:
    - changes in serum composition (e.g. TP, bilirubin, cholesterol; Biochemical: Neurotransmitters or modulators (putative): catecholamine levels in CNS
  - TDLo (Subcutaneous-Rat) 280 mg/kg/7 days-intermittent: Kidney/Ureter/Bladder: changes in bladder weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases
  - TDLo (Subcutaneous-Mouse) 560 mg/kg/7 days-intermittent: Gastrointestinal: other changes; Kidney/Ureter/Bladder: other changes in urine composition
  - TDLo (Subcutaneous-Monkey) 500 mg/kg/5 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Kidney/Ureter/Bladder: other changes in urine composition

**NEOMYCIN SULFATE (continued):**

- TDLo (Intramuscular-Cat) 5050 mg/kg/14 weeks-intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis), interstitial nephritis; Related to Chronic: Death
- TDLo (Intramuscular-Guinea Pig) 2 gm/kg/8 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Related to Chronic: Death

**POLYMIXIN B SULFATE:**

- LD₅₀ (Oral-Mouse) 790 mg/kg
- LD₅₀ (Intraperitoneal-Mouse) 20,500 mg/kg
- LD₅₀ (Subcutaneous-Mouse) 59,500 mg/kg
- LD₅₀ (Subcutaneous-Guinea Pig) 58 mg/kg
- LD₅₀ (Intravenous-Mouse) 5400 mg/kg
- LD₅₀ (Intravenous-Dog) 8 mg/kg
- TDLo (Intracerebral-Dog) 320 μg/kg: Behavioral
- LD₅₀ (Subcutaneous-Mouse) 284 mg/kg/9 days-intermittent: Behavioral: muscle weakness Skin and Appendages: dermatitis, other (after systemic exposure); Skin and Appendages: hair
- DNA Adduct (Bacteria-Escherichia coli) 50 μg/mL
- Mutation Test Systems-Not Otherwise Specified (Microorganism-Not Otherwise Specified) 25 μg/mL
- Mutation Test Systems-Not Otherwise Specified (Yeast-Saccharomyces cerevisiae) 5 mg/L

CARCINOGENIC INFORMATION: The 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.

The effect of oral administration of Neomycin (100 and 200 μg/mL in drinking water) on colon tumors induced by azoxymethane (AOM) was studied in female F344 rats. 5-week-old rats were fed NIH-07 diet and given daily in drinking water 0, 100, and 200 μg neomycin/ml. At 7 weeks of age, all animals except vehicle-treated groups received weekly sc injections of 8 mg AOM/kg bw for 8 weeks. The AOM- or vehicle-treated groups were necropsied 30 weeks after the last injection of AOM. The combined incidence of adenomas and adenocarcinomas of the colon did not differ significantly among the 3 groups. The animals in the groups given 100 and 200 μg neomycin had a higher incidence of colon adenocarcinomas than did those in the control group. Colonic and cecal bacterial beta-glucuronidase activity was significantly lower in the group given 200 μg Neomycin than it was in the control group. The excretion of fecal cholesterol, total bile acids, and deoxycholic acid was increased significantly in animals given 100 and 200 μg Neomycin as compared to animals given no Neomycin. These results suggest that long-term oral administration of neomycin increases the incidence of colon adenocarcinomas.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate on animal and human reproductive systems.

**Mutagenicity:** The components of this product are not reported to cause mutagenic effects in humans.

**Embryotoxicity:** Studies have not been performed to evaluate the embryotoxic effects of this product.

**Teratogenicity:** Aminoglycoside antibiotics, such as Neomycin and Polymyxin B Sulfates, cross the placenta and may cause total, irreversible, bilateral, congenital deafness in children.
11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Reproductive Toxicity: Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on male or female fertility, litter size, or survival were observed in rabbits given Bacitracin Zinc 100 g/ton of diet.

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

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, 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.

ENVIRONMENTAL STABILITY: This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption or mobility.

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

EFFECT OF CHEMICAL ON AQUATIC LIFE: Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

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 drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

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

14. TRANSPORTATION INFORMATION

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.

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

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

U.S. TSCA INVENTORY STATUS: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.
15. REGULATORY INFORMATION (Continued)

UNITED STATES REGULATIONS (continued):
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): When used internally, the Neomycin Sulfate component of this product is on the California Proposition 65 lists as a compound that is known to cause developmental harm.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

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

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: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOLS:
Class D2B Poisonous and infectious material (Sensitization)

16. OTHER INFORMATION

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

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DEFINITION OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:
CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

EXPOSURE LIMITS IN AIR:
CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens that have been shown to increase the mutation frequency in the progeny of exposed humans. 2: Germ cell mutations that have been shown to increase the mutation frequency in the progeny of exposed mammals. 3A: Substances that have shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals in vivo and have been shown to reach the germ cells in an active form. 3B: Substances that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell in vivo; in exceptional cases, substances for which there are no in vivo data, but that are clearly mutagenic in vitro and structurally related to known in vivo mutagens. 4: Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action). By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g., purely aneugenic substances] if research results make this seem sensible.) 5: Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed.

EXPOSURE LIMITS IN AIR (continued):

PEL: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforced by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the MAK and BAT values are observed.

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

NIC: Notice of Intended Change.

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

NIOSH RELs: NIOSH's Recommended Exposure Limits.
EXPOSURE LIMITS IN AIR (continued):
SKIN: Used when there is a danger of cutaneous absorption.
STEL: Short Term Exposure Limit, usually a 15-minute-time-weighted average (TWA) but may not be exceeded at any time during a working day, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA. TWA: Time Weighted Average exposure concentration for a conventional 8-hr (TWA), PEL or up to a 10-hr (REL) workday and a 40-hr workweek.
WEEL: Weekly or Seasonal Exposure Limits established by the AHA.

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. PII or Draize = 0. Eye Irritation: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. Oral Toxicity LD₅₀: > 5,000 mg/kg. Inhalation Toxicity: 4-hrs LC₅₀: > 20 mg/L. Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may defect the skin and exacerbate existing dermatitis. Skin Irritation: Slightly or mildly irritating. PII or Draize > 0. Eye Irritation: Temporary or transitory injury may occur; may cause permanent eye damage if not treated appropriately. 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 6–21 days. Draize > 26–100, with reversible effects. Inhalation Toxicity: LC₅₀: > 50–500 mg/L. Dermal Toxicity LD₅₀: Rat or Rabbit > 200–1000 mg/kg. Inhalation Toxicity LC₅₀: 4-hrs Rat > 0.5–2 mg/L. Slight 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 dermal 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 > 1–50 mg/kg. Dermal Toxicity LD₅₀: Rabbit > 20–50 mg/kg. Inhalation Toxicity LC₅₀: 4-hrs Rat > 0.05–0.5 mg/L. Slight Hazard: Life-threatening; major or permanent damage may result from single or repeated exposures; 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: Not appropriate. Do not rate as a 4, based on eye irritation alone.

Flammable liquids: Division 3.3 flammables. Explosives: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire may cause instantaneous explosion of more than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 aqueous sodium chloride solution (40%)/cellulose mixture and the criteria for Packing Group I and II are not met. Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, and have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at ambient temperature and pressure, and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen under pressure, and have a high potential (or high risk) to cause significant heat generation or explosion. NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

FLAMMABILITY HAZARD: 4 (continued) This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that will migrate to a flash point or boil point below 73.8°C (165°F); and a boiling point below 37.8°C (100°F) (i.e. OSHA Class IIA); and Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric).

PHYSICAL HAZARD: 0 Water Reactivity: Materials that do not react with water. Organic Peroxides: Materials that are normally stable, even under fire conditions and will not react with water. Explosives: Substances that are Non-Explosive. Compressed Gases: No Rating. Pyrophorics: No Rating. Oxidizers: No 0 rating. Organic Peroxides: Substances that will not polymerize, decompose, condense, or self-react. 1 Water Reactivity: Materials that change or decompose upon exposure to moisture. Organic Peroxides: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. Explosives: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. Compressed Gases: Pressure below OSHA definition. Pyrophorics: No Rating. Oxidizers: Packaging Group III oxidizers; Solids: any material that, in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3.7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 aqueous sodium chloride solution (40%)/cellulose mixture and the criteria for Packing Group I and II are not met.

Toxicity LD₅₀: Rat or Rabbit > 500–5000 mg/kg. Inhalation Toxicity LC₅₀: 4-hrs Rat > 0.5–2 mg/L. Minimal Hazard: Materials that will not burn in air when exposed to an ambient temperature of 81°C (178°F) for a period of 5 minutes. 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 ignite spontaneously to a temperature of 150°C (302°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 IIA); and Materials that ignite spontaneously to a temperature of 150°C (302°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 IIB); 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 temperatures 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 a fibrous or shredded form that may burn rapidly and may not be expected to be ignited at any time during a working day, even if the 8-hr TWA is within the TLY-TWA, PEL-TWA or REL-TWA.

Water Reactivity: Materials that may react violently with water. Organic Peroxides: Materials that, in themselves, are normally unstable and will readily undergo chemical change, but do not detonate. These materials may also react violently with water. Explosives: Division 1.4 explosives. Explosive substances whose water-reactive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire may cause instantaneous explosion of almost the entire contents of the package. Compressed Gases: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [50 psig]. Pyrophorics: No Rating. Oxidizers: Packaging Group II oxidizers. Solids: any material that, in either concentration tested, exhibits a mean pressure rise time of less than or equal to the mean burning time of a 2.3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 aqueous sodium chloride solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, and have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen under pressure, and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.
DEFINITION OF TERMS (Continued):

FLAMMABILITY HAZARD: 4 Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, showing a flash point at or below 25°C (77°F) and a boiling point below 85°C (185°F). Gases with an LDo less than 200 ppm that can form an ignitable mixture with air. Bulk liquids with an LDo less than or equal to 1000 ppm. Solids that in themselves are readily capable of sustained combustion in air under almost all ambient conditions. Materials that in themselves are combustible at normal temperatures and pressures. Materials that in themselves are capable of causing a fire which cannot be extinguished by water. Materials that in themselves are capable of causing an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) or at above 0.01 W/mL and below 10 W/mL. Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) or at above 0.01 W/mL and below 1000 W/mL. Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require 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) or at above 10 W/mL and below 10 000 W/mL. Materials that exhibit an exotherm at temperatures less than or equal to 100°C (212°F) when tested by differential scanning calorimetry.