Shield Line

MATERIAL SAFETY DATA SHEET

May 2, 2013

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

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Medpride Triple Antibiotic Ointment

DESCRIPTION: Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate Ointment
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): $C_{66}H_{103}N_{17}O_{16}S/C_{23}H_{46}N_6O_{13}\cdot 3H_2O_4S$ /$C_{43}H_{82}N_{16}O_{12}\cdot H_2O_4S$
PRODUCT USE: Pharmaceutical for Human Use

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 situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CAS # % w/w

CHEMICAL NAME

3. COMPOSITION and INFORMATION ON INGREDIENTS CHEMICAL NAME Each gm contains:	CAS #	% w/w
Bacitracin Zinc	1405-87-4	400 Units
Neomycin Sulfate	1405-10-3	3.5 mg
Polymyxin B Sulfate	1405-20-5	5000 Units
White Petrolatum	8009-03-8	Proprietary

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 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. 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, %): Not applicable.

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

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL 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 Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

ADVICE TO 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

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

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).

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:

CHEMICAL NAME	*CAS #*	*EXPOSURE LIMITS IN AIR*							
		ACGIH-TLVs		*OSHA-PELs*		*NIOSH-RELs*		*NIOSH*		*OTHER*
		TWA	*STEL*	*TWA*	*STEL*	*TWA*	*STEL*	*TWA*	*STEL*	*IDLH*
		mg/m3	*mg/m3*	*mg/m3*	*mg/m3*	*mg/m3*	*mg/m3*	*mg/m3*	*mg/m3*	*mg/m3*
Bacitracin Zinc	1405-87-4	NE	NE	NE	NE	NE	NE	NE	NE	NE
Neomycin Sulfate	1405-10-3	NE	NE	NE	NE	NE	NE	NE	NE	NE
Polymyxin B Sulfate	1405-20-5	NE	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE	NE

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).

EYE PROTECTION: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-07.

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

BOILING POINT: 200°C (392°F) ***FREEZING/MELTING POINT:*** 58°C (136°F)

EVAPORATION RATE (nBuAc = 1): 0 ***SOLUBILITY IN WATER:*** Insoluble.

VAPOR PRESSURE (air = 1): < 1 mm Hg ***SPECIFIC GRAVITY @ 60°C (water = 1):*** 0.85

ODOR THRESHOLD: Not established. ***pH:*** Not established.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

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

REACTIVITY/CHEMICAL 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.

11. TOXICOLOGICAL INFORMATION (Continued)

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, apnea, 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. 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.

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 are presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS, contact Shield Line for more information.

BACITRACIN ZINC:

LD_{50} (Oral-Mouse) > 3750 mg/kg

LD_{50} (Oral-Guinea Pig) 2 gm/kg

LD_{50} (Oral-Quail) > 316 mg/kg

LD_{50} (Intraperitoneal-Rat) 190 mg/kg: Lungs, Thorax, or Respiration: other changes

LD_{50} (Intraperitoneal-Mouse) 300 mg/kg

LD_{50} (Subcutaneous-Mouse) 1300 mg/kg: Behavioral: somnolence (general depressed activity)

LD_{50} (Intravenous-Mouse) 360 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: other changes

BACITRACIN ZINC (continued):

TCLo (Skin-Human) 20 pph/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

NEOMYCIN SULFATE (continued):

TCLo (Skin-Human) 20 pph/48 hours-continuous: Skin and Appendages: dermatitis, allergic (after topical exposure)

LD_{50} (Oral-Mouse) > 8 gm/kg

LD_{50} (Subcutaneous-Rat) 200 mg/kg

LD_{50} (Subcutaneous-Mouse) 190 mg/kg

LD_{50} (Intraperitoneal-Mouse) 305 mg/kg

LD_{50} (Intravenous-Mouse) 17,400 µg/kg

LD_{50} (Intramuscular-Mouse) 142 mg/kg: Behavioral: convulsions or effect on seizure threshold

LD_{50} (Intramuscular-Guinea Pig) > 250 mg/kg: Ear: change in acuity

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

NEOMYCIN SULFATE (continued):

LD_{50} (Intracerebral-Mouse) 32 mg/kg

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; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

NEOMYCIN SULFATE (continued):

TDLo (Intramuscular-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

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 Data: 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 Data: death

TDLo (Intraspinal-Rat) 36.88 µg/kg: Behavioral: analgesia

POLYMIXIN B SULFATE:

LD_{50} (Oral-Mouse) 790 mg/kg

LD_{50} (Intraperitoneal-Mouse) 20,500 µg/kg

LD_{50} (Subcutaneous-Mouse) 59,500 µg/kg

LD_{50} (Subcutaneous-Guinea Pig) 58 mg/kg

LD_{50} (Intravenous-Mouse) 5400 µg/kg

LDLo (Intravenous-Dog) 8 mg/kg

LDLo (Intracerebral-Dog) 320 µg/kg: Behavioral-coma

TDLo (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 mg/L

Mutation Test Systems-Not Otherwise Specified (Microorganism-Not Otherwise Specified) 25 mg/L

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 (0, 100, and 200 ppm). 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 or human reproductive systems.

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

Teratogenicity: Aminoglycoside antibiotics, such as Neomycin and Polymyxin B Sulfates, cross the placenta and may cause total, irreversible, bilateral, congenital deafness in children.

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.

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.

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.

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.

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.

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.

16. OTHER INFORMATION

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, CO_2, 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.