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

DESCRIPTION: Nystatin, Neomycin Sulfate, Thiostrepton, and Triamcinolone Acetonide Ointment
NDC #: 15 mL: 17033-122-15; 240 mL: 17033-133-24; 30 mL: 17033-122-30; 7.5 mL: 17033-122-75
CHEMICAL NAME (for active ingredients):
- For Nystatin: (21E,23E,25E,27E,31E,33E)-20-[(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy]-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid
- For Neomycin Sulfate: 2-deoxy-4-O-(2,6-diamino-2,5-dideoxy-α-D-glucopyranosyl)-5-O-[3-O-(2,6-dideoxy-β-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine
- For Thiostrepton: (21E,23E,25E,27E,31E,33E)-20-[[[(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy]-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid
- For Triamcinolone Acetonide: Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxyl-16,17-[(1-methylethyldiene)bis(oxy)]-{(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl}oxy]-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid

CHEMICAL FAMILY (for active ingredients):
- For Nystatin: Aminoglycoside
- For Neomycin Sulfate: Aminoglycoside
- For Thiostrepton: Oligopeptide
- For Triamcinolone Acetonide: Corticosteroid

FORMULA (for active ingredients):
- For Nystatin: C_{29}H_{36}N_{2}O_{6}
- For Neomycin Sulfate: C_{22}H_{33}N_{2}O_{6}S
- For Thiostrepton: C_{37}H_{60}N_{2}O_{6}S
- For Triamcinolone Acetonide: C_{29}H_{31}FO_{6}

HOW SUPPLIED: 7.5, 15, 30 and 240 mL tubes containing 0.25% Neomycin Sulfate, 0.1% Triamcinolone Acetonide, 100,000 units Nystatin and 2500 units Thiostrepton per mL

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 yellow to tan ointment with a faint waxy odor. This product is a veterinary product used in treatment of dogs and cats and is not used therapeutically in humans. The following possible health hazards information is for humans and is based on information for active ingredients when used in human health care. Health Hazards: In the workplace, exposure via eye contact may cause irritation. Prolonged skin contact may cause redness or skin discomfort. Ingestion may be harmful. Inhalation is unlikely due to viscosity. Exposure may cause acnec-like eruptions, burning, dryness, excessive hair growth, infection of the skin, irritation, itching, lack of skin color, prickly heat, skin inflammation, skin loss or softening, or stretch. Chronic exposure can cause adverse effects on the immune and adrenal systems and eyes. Chronic exposure can result in increased susceptibility to infections and may exacerbate systemic fungal infections. Rare instances of anaphylactoid reactions have occurred in persons receiving corticosteroid therapy; these reactions may also occurred to susceptible individuals handling this product. Allergic reactions may be severe and can be life-threatening in certain individuals. Limited evidence of harm to the fetus, based on animal information for the active ingredients. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for information on other potential health hazards known for the active ingredients. Flammability Hazards: This product is combustible and may ignite if exposed to direct flame or if highly heated for a prolonged period. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds, including carbon and nitrogen oxides, sulfur compounds and hydrogen fluoride. Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects. 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>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>215-773-1</td>
<td>0.025%</td>
<td>SELF-CLASSIFICATION</td>
</tr>
<tr>
<td>Triamcinolone Acetonide</td>
<td>78-25-5</td>
<td>200-948-7</td>
<td>0.1%</td>
<td>SELF-CLASSIFICATION</td>
</tr>
<tr>
<td>Thiostrepton</td>
<td>1400-61-9</td>
<td>215-749-0</td>
<td>100,000 units</td>
<td>SELF-CLASSIFICATION</td>
</tr>
<tr>
<td>Ethylene Homopolymer</td>
<td>9002-88-4</td>
<td>Not Listed</td>
<td>Proprietary</td>
<td>GHS Under U.S. OSHA &amp; EU CLP 2008: No Classification Applicable</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8042-47-5</td>
<td>232-455-8</td>
<td>Balance</td>
<td>SELF-CLASSIFICATION</td>
</tr>
</tbody>
</table>

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 cardiac-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, 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 skin conditions, hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing’s syndrome, hyperglycemia, and glucosuria, renal insufficiency, gastrointestinal disease or cardiovascular disease, liver, kidney conditions and hearing problems may be aggravated by repeated exposure to this product. In therapeutic use, pre-existing endocrine conditions, existing fungal infections, glaucoma, high blood sugar, or bone density problems may be aggravated. Dehydration increases the toxicity of Neomycin Sulfate. Workplace exposure may aggravate these conditions. Persons who may have hypersensitivity reactions to aminoglycosides or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.
4 FIRST-AID MEASURES (Continued)

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 available for this product. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.
AUTOIGNITION TEMPERATURE: Not established.
FLAMMABLE LIMITS (in air by volume, %): Not applicable. Not applicable.
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product is combustible. If heated to high temperatures for a prolonged period it may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic gases (e.g., carbon and nitrogen oxides, sulfur compounds and hydrogen fluoride).

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

ENVIRONMENTAL PRECAUTIONS: Prevent 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 veterinary practices and following the recommendations presented on the Package Insert.
7. HANDLING and USE (Continued)

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 veterinary drug.

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 poly pad. 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>ACGIH TLVs</th>
<th>OSHA PELs</th>
<th>NIOSH RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
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<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>NE</td>
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<td>NE</td>
<td>5 NE</td>
<td>10 NE</td>
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</tr>
</tbody>
</table>

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

International Occupational Exposure Limits: The following additional international exposure limits are available for some components.

TRIAMINOLONE ACETONIDE:
- Russia: STEL = 0.001 mg/m³, JUN 2003
- MINERAL OIL:
  - Australia: TWA = 5 mg/m³, JUL 2008
  - Belgium: TWA = 5 mg/m³, STEL = 10 mg/m³, MAR 2002
  - Denmark: TWA = 1 mg/m³, MAY 2011
  - Hungary: CL = 5 mg/m³, Carcinogen, SEP 2000
  - Japan: OEL = 3 mg/m³ (mist), 1 carc. MAY 2012
  - Korea: TWA = 5 mg/m³, STEL = 10 mg/m³, 2006
  - Mexico: TWA = 5 mg/m³, STEL = 10 mg/m³, 2004
  - New Zealand: TWA = 5 mg/m³, STEL 10 ppm, JAN 2002
  - The Philippines: TWA = 5 mg/m³, JAN 1993
  - Poland: MAC(TWA) = 5 mg/m³, MAC(STEL) = 10 mg/m³, JAN 1999
  - Russia: STEL = 5 mg/m³, JUN 2003
  - Sweden: TWA = 1 mg/m³, STEL = 3 mg/m³, JUN 2005
  - In Argentina, Bulgaria, Colombia, Jordan, Korea, New Zealand, Singapore, Vietnam, New Zealand, Singapore, Vietnam check ACGIH TLV

POLYETHYLENE:
- Russia: STEL = 10 mg/m³, JUN 2003


Please reference applicable regulations and standards for relevant details.

Respiratory Protection: Not typically needed under normal circumstances of handling and use. 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.

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.
8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT (continued):

Hand Protection (continued): Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

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

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Ointment. COLOR: Yellow to tan.
MOLECULAR WEIGHT: Mixture. MOLECULAR FORMULA: Mixture.
ODOR: Slight, waxy. ODOR THRESHOLD: Not established.
BOILING POINT: 150°C (302°F) MELTING POINT: Not available.
EVAPORATION RATE (nBuAc = 1): Not established. pH: 4.0-5.5
SOLUBILITY IN WATER: Partially soluble. OTHER SOLUBILITIES: Not available.
VAPOR PRESSURE (air = 1): Not established. SPECIFIC GRAVITY @ 20°C (water = 1): 0.87
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance may be a property to identify the product 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 and nitrogen oxides, sulfur compounds and hydrogen fluoride).

Hydrolysis: None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, strong oxidizers, water reactive materials, and other chemicals that could affect its performance should be avoided.

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat 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 veterinary employees handling this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation is unlikely due to viscosity. If aerosols are somehow generated and inhaled, irritation of the nose and upper respiratory system may occur. Symptoms of such exposure may include sneezing, coughing, and nasal congestion. In persons susceptible to corticosteroids, inhalation can cause bronchospasm, with an immediate increase in wheezing. Glaucma, increased intraocular pressure, and cataracts have been reported following the long-term inhalation of corticosteroids.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Aminoglycosides have a low order of toxicity in contact with skin; however, rashes and allergic anaphylactoid reactions have occurred in susceptible persons. 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. Symptoms of eye contact may include redness, pain, and watering.

Skin Absorption: This product can be absorbed into the skin. Symptoms of chronic exposure by this route may include reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine. Neomycin Sulfate 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, Neomycin Sulfate is a nephrotoxic antibiotic (can cause damage to the liver), and the nephrotoxic potentials are additive. Persons handling this product routinely in an animal medical facility should be gloved.

Animax® Ointment SDS 
EFFECTIVE DATE: OCTOBER 22, 2015
11. TOXICOLOGICAL INFORMATION (Continued)

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE (continued):

Ingestion: Ingestion of this product is not anticipated to be a significant route of occupational exposure. Ingestion of this product (i.e., through poor hygiene practices) may be harmful or irritate the mouth, throat, and other tissues of the gastrointestinal system. Symptoms can include nausea, vomiting, diarrhea and inflammation of the small intestine and the colon. Although ingestion of Neomycin Sulfate may cause severe allergic reactions, reactions are rare. Neuromuscular blockage and respiratory paralysis have been reported following the oral use of Neomycin. 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 necrosis, kidney damage, hearing loss, and hair loss. Chronic ingestion can also cause reduction in bone density, immune and adrenal system suppression, and Candida infections due to the Triamcinolone Acetonide component.

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.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue, especially if contact is prolonged.

SENSITIZATION OF PRODUCT: Aminoglycosides have a low order of toxicity in contact with skin; 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. Rare instances of anaphylactoid reactions have occurred in persons susceptible to corticosteroids. Nystatin has caused bronchospasm, facial swelling, rash, hives (rarely), and Stevens-Johnson (very rarely) have been reported.

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

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

Chronic: Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause symptoms as described earlier in this Section.

TARGET ORGANS:

Acute: Skin.

Chronic: Skin, adrenal system, metabolic system, fetal harm.

TOXICITY DATA: Only toxicity data available for the active components of this product are presented in this SDS. Additional data are available for the excipient components of this product, but are not presented in this SDS; Contact Fougera for more information.

NEOMYCIN SULFATE:
Standard Draize Test (Skin-Human) 6 mg/3 days intermittent: Mild
Standard Draize Test (Skin-Human) 0.2%: Severe
TDLo (Oral-Human) 12,600 mg/kg/7 days: Behavioral: somnolence (general depressed activity), hallucinations, distorted perceptions, anorexia (human)
LD50 (Oral-Mouse) > 8 gm/(base)/kg
LD50 (Subcutaneous-Rat) 200 mg/kg
LD50 (Subcutaneous-Mouse) 190 mg/kg
LD50 (Intraperitoneal-Mouse) 305 mg/kg
LD50 (Intravenous-Mouse) 17,400 µg/kg
LD50 (Intramuscular-Mouse) 142 mg/kg
LD50 (Intramuscular-Guinea Pig) > 250 mg/kg: Sense Organs and Special Senses (Ear); change in auditory response
LD50 (Intracerebral-Mouse) 32 mg/kg
LD50 (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
LD50 (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
LD50 (Intravenous-Rat) 15 mg/kg: Behavioral: alteration of classical conditioning
LD50 (Intraspinal-Rat) 36.88 mg/kg: Behavioral: analgesia
LD50 (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
LDLo (Intramuscular-Monkey) 500 mg/kg/5 days intermittent: Sense Organs and Special Senses (Ear); change in auditory response, changes in cochlear structure or function; Kidney/Ureter/Bladder: other changes in urine composition
TDLo (Intramuscular-Rat) 3500 µg/kg/14 weeks intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis), interstitial nephritis; Related to Chronic Data: death
LDLo (Intramuscular-Guinea Pig) 2 gm/kg/8 days intermittent: Sense Organs and Special Senses (Ear); change in auditory, changes in cochlear structure or function; Related to Chronic Data: death

NYSTATIN (continued):
TDLo (Intravenous-Rat) 42 mg/kg/4 weeks intermittent: Behavioral: food intake (animal); Skin and Appendages; hair; Nutritional and Gross: Metabolic: weight loss or decreased weight gain
TDLo (Intravenous-Rat) 82.5 mg/kg/55 days intermittent: Behavioral: food intake (animal); Nutritional and Gross: Metabolic: weight loss or decreased weight gain
TDLo (Intravenous-Rat) 61.5 mg/kg/41 days intermittent: Nutritional and Gross: Metabolic: weight loss or decreased weight gain
LDLo (Intravenous-Rat) 90 mg/kg/41 days intermittent: Behavioral: food intake (animal)
LDLo (Intravenous-Rat) 55.5 mg/kg/37 days intermittent: Behavioral: food intake (animal); Nutritional and Gross: Metabolic: weight loss or decreased weight gain
LDLo (Intravenous-Rat) 87 mg/kg/37 days intermittent: Related to Chronic Data: death
LDLo (Intravenous-Rat) 30 mg/kg/10 days intermittent: Behavioral: food intake (animal)
LDLo (Intravenous-Rat) 18500 µg/kg: female 6-22 day(s) after conception lactating female 20 day(s) post-birth: Reproductive: Maternal Effects: other effects: Effects on Newborn: growth statistics (e.g.%, reduced weight gain), physical
LDLo (Intravenous-Rat) 18.5 mg/kg: female 6-22 day(s) after conception lactating female 20 day(s) post-birth: Reproductive: Specific Developmental Abnormalities: eye/ear, other development abnormalities; Effects on Newborn: growth statistics (e.g.%., reduced weight gain)
LDLo (Intravenous-Rat) 30 mg/kg: female 6-15 day(s) after conception: Reproductive: Maternal Effects: other effects
LDLo (Intravenous-Rat) 55.5 mg/kg: female 6-22 day(s) after conception lactating female 20 day(s) post-birth: Reproductive: Specific Developmental Abnormalities: urogenital system
LDLo (Intravenous-Rat) 30 mg/kg: female 6-15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: feototoxicity (except death, e.g., stunted fetus)
LDLo (Intravenous-Rabbit) 39 mg/kg/13 days intermittent: Behavioral: food intake (animal); Liver: changes in liver weight
LDLo (Intravenous-Rabbit) 39 mg/kg: female 6-18 day(s) after conception: Reproductive: Maternal Effects: other effects
LDLo (Intravenous-Mammal-Dog) 180 mg/kg/90 days intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis); Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol)
LDLo (Subcutaneous-Rat) 0.053 gm/kg: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TCLo (Inhalation-Rat) 5 mg/m3/4 hours /17 weeks intermittent: Immunological Including Allergic: hypersensitivity delayed
TCLo (Inhalation-Rat) 40 mg/m3/24 hours /10 days-continuous: Immunological Including Allergic: decrease in humoral immune response; Biochemical: Metabolism (Intermediary): Plasma proteins not involving coagulation
TCLo (Inhalation-Guinea pig) 5 mg/m3/3 hours /17 weeks- intermittent: Immunological Including Allergic: hypersensitivity delayed

Cytogenetic Analysis (Parenteral-Mouse) 50 mg/kg
TOXICITY DATA (continued):

TRIAMCINOLONE ACETONIDE:

Standards Draize Test (Skin-Woman) 0.1% 2 days
Standard Draize Test (Skin-Woman) 1% Moderate
Standard Draize Test (Skin-Woman) 0.01%: Mild

TDLo (Skin-Woman) 1.7 µg/kg/8 days-intermittent: Skin and Appendages: dermatitis, other (systemic exposure)

TDLo (Skin-Woman) 100 µg/kg: female 12-29 week(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: gastroduodenal system

TDLo (Intramuscular-Mouse) 571 µg/kg: Vascular: shock; Skin and Appendages: dermatitis, other (after systemic exposure); Immunological Including Allergic: anaphylaxis

TDLo (Parenteral-Woman) 4 µg/kg: Behavioral: muscle weakness; Vascular: BP elevation not characterized in autonomic section

LDLo (Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: Central Nervous System, other developmental abnormalities

LDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Effects on Embryo or Fetus: other effects to embryo

L(Oral-Mouse) 1 mg/kg: female 14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: Central Nervous System, other developmental abnormalities

TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: cytological changes (including somatic and germinal material)

TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Effects on Embryo or Fetus: other effects to embryo

TOXICOLOGICAL INFORMATION (Continued):

CARCINOGENIC INFORMATION: The following information is available for the active ingredients

Neomycin Sulfate: 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 body weight 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.

Neomycin: 11. TOXICOLOGICAL INFORMATION (Continued):

TDLo (Ocular-Rabbit) 0.95 µg/mL: Sense Organs and Special Senses (Eye): corneal damage

TDLo (Intramuscular-Rat) 375 µg/kg: female 12-14 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)

TDLo (Intramuscular-Rat) 500 µg/kg: female 14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue),其它 developmental abnormalities

TDLo (Intramuscular-Rat) 750 µg/kg: female 12-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: body wall

TDLo (Intramuscular-Rat) 1000 µg/kg: female 12-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (Intramuscular-Mouse) 480 µg/kg: female 11 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo

TDLo (Intramuscular-Mouse) 5 mg/kg: female 11 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: Central Nervous System, other developmental abnormalities

TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: cytological changes (including somatic and germinal material)

TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Effects on Embryo or Fetus: other effects to embryo

TDLo (Intramuscular-Hamster) 500 µg/kg: female 9 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: Central Nervous System, other developmental abnormalities

TDLo (Intramuscular-Hamster) 100 µg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo

TDLo (Intramuscular-Hamster-Mouse) 50 mg/kg: female 23-31 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue),其它 developmental abnormalities

TDLo (Intramuscular-Mouse) 60 mg/kg: female 41-44 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue),其它 developmental abnormalities

TDLo (Intramuscular-Mouse) 250 µg/kg: female 12-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)

TDLo (Intramuscular-Mouse) 100 µg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Mouse) 2500 µg/kg: female 12-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Mouse) 10 µg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death; Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Mouse) 250 µg/kg: female 12-14 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC INFORMATION (continued):

Nystatin: No long-term animal studies have been performed to evaluate carcinogenic potential of Nystatin.
Triamcinolone Acetonide: Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids.

The Polyethylene component is listed by agencies tracking the carcinogenic potential of chemical compounds as follows.

- **Polyethylene**: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

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: The following information is available for some active ingredients.

**Mutagenicity:** No studies available.

- Neomycin Sulfate: Studies in humans have not been performed with the aminoglycosides, including Neomycin Sulfate to determine potential mutagenic effect. Treatment of cultured human lymphocytes *in vitro* with Neomycin increased the frequency of chromosome aberrations at the highest concentrations (80 µg/mL) tested; however, the effects of Neomycin on mutagenesis in humans are unknown.

- Nystatin: Negative: N. crassa—aneploidy. No other studies to determine mutagenicity located.

**Embryotoxicity/Teratogenicity:**

- Neomycin Sulfate: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and have been several reports of total irreversible, 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.

- Nystatin: Adequate animal reproduction studies have not been conducted with Nystatin. It is also not known whether Nystatin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Refer to specific animal reproductive toxicity data given earlier in this Section under ‘Toxicity Data’.

**Triamcinolone Acetonide:**

- **Human Data:** As a group, corticosteroids have not been associated with congenital malformations in humans.
- **Animal Data:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

**Reproductive Toxicity:** No human adverse effects on fertility have been described for this product. 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.

- Neomycin Sulfate: No long-term animal studies have been performed with Neomycin Sulfate to evaluate impairment of fertility. It is not known whether neomycin is excreted in human milk, but it has been shown to be excreted in cow milk following a single intramuscular injection. Other aminoglycosides have been shown to be excreted in human milk.

- Nystatin: There have been no studies to whether Nystatin affects fertility in males or females. It is not known whether Nystatin is excreted in human milk.

**Triamcinolone Acetonide:** Corticosteroids are secreted in human milk. Because of the potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

**Non-Teratogenic Effects:** Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy.

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

12. ECOCLOGICAL 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 in formation 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 aquatic toxicity data are available for some active ingredients.

**NYSTATIN:**

EC<sub>50</sub> (Green algae) 72 hours = 1 µg/mL (= 0.001 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.
13. DISPOSAL CONSIDERATIONS (Continued)

DISPOSAL METHODS (continued): 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: 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 SHIPPI NG 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): The Neomycin Sulfate component is listed on the California Proposition 65 lists; however, this listing applies when Neomycin Sulfate is used internally and does not apply to this product. Aminoglycosides are listed on the California Proposition 65 lists. WARNING! This product contains a compound known to the State of California 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.

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.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING!
INGESTION MAY BE HARMFUL. PROLONGED SKIN CONTACT MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE RESPIRATORY SYSTEM AND EYE IRRITATION. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY, BASED ON ANIMAL DATA. MAY BE COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not touch or swallow. Avoid skin or contact with clothing. 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 CLP 1272/2008: Global Harmonization:**

Neomycin Sulfate: This is a self-classification.

**Classification:** Reproductive Toxicity Category 2, Skin Sensitization Category 1A, Respiratory Sensitization Category 1B, Skin Irritation Category 2, Eye Irritation Category 2A, Specific Target Organ Toxicity Repeated Exposure Category 2

**Hazard Statements:**

H361: Suspected of damaging fertility or the unborn child. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. H373: May cause damage to the liver through prolonged or repeated exposure.

Nystatin: The following is a Self-Classification.

**Classification:** Reproductive Toxicity Category 2, Aquatic Acute Toxicity Category 1

**Hazard Statements:**

H361d: Suspected of damaging the unborn child. H400: Very toxic to aquatic life.

Thiostrepton: The following is a Self-Classification.

**Classification:** Acute Oral Toxicity Category 4

**Hazard Statements:**

H302: Harmful if swallowed.

Triaminolone Acetonide: The following is a Self-Classification.

**Classification:** Reproductive Toxicity Category 2, Acute Oral Toxicity Category 4, Skin Irritation Category 2, Specific Target Organ Toxicity (Dermal-Multiple Organs) Repeated Exposure Category 2

**Hazard Statements:**

H361d: Suspected of damaging the unborn child. H302: Harmful if swallowed. H315: Causes skin irritation. H373: May cause damage to organs (bones, eyes, immune and adrenal systems) through prolonged or repeated exposure by skin contact.

Mineral Oil: The following is a Self-Classification.

**Classification:** Aspiration Hazard Category 1

**Hazard Statements:**

H304: May be fatal if swallowed and enters airways.

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

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

**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 working exposure.

**DFG MAK**

**Germ Cell Mutagen Categories:**

1: Germ cell mutations that have been shown to increase the mutation frequency in the progeny of exposed mammals. 3A: Substances that have been shown to induce genetic damage in germ cells of human 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 mutants are genotoxic. Therefore, a Category 4 for germ cell mutants 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.

**DEFINITION OF TERMS**

**EXPOSURE LIMITS IN AIR (continued):**

**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. Group B: Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. Group C: There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. Group D: Classification in one of the groups A–C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

**IDHL:** 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:** Limit of Quantitation.

**MAK:** Federal Republic of Germany Maximum Concentration Values in the workplace.

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

**NIC:** Notice of Intended Change.
EXPOSURE LIMITS IN AIR (continued):

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 time-weighted average (TWA) exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELs: NIOSH’s Recommended Exposure Limits.

PEL: Occupational Exposure Limits. The exposure value means exactly the same as a TLV, except that it is enforceable 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 current PELs and the vaccinated TWA PELs have been designated as “OSHA-Approved PELs.” The phrase, “Vacated 1989 PEL” is placed next to the PEL that was vacated by Court Order.

SKIN: Used when there is a danger of cutaneous absorption.

STEL: Short-Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hour TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

TLV: The Recommended Standard for an occupational exposure to a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour, TWA: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or 24-hr period (REL). The time-weighted average exposure for a 24-hour period is calculated as the integral of the concentration-time product of the exposure over the entire 24-hour period, divided by the number of hours of the period. For an 8-hour period, the time-weighted average is calculated as the integral of the concentration-time product of the exposure over the entire 8-hour period, divided by 8.

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS: This rating system was developed by the National Paint and Coating Association to provide the paint, coating and solvent user industry with a one-page system to identify the degree of chemical hazards.

HEALTH HAZARD: 0 Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. Essentially non-irritating to the package user or laboratory animal. Inert or nonreactive. P II or Draize = 0. Eye Irritation: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. Oral Toxicity LD sub 50 = > 5000 mg/kg. Dermal Toxicity LD sub 50 = > 2000 mg/kg. Inhalation Toxicity LC sub 50 = > 20 mg/L. Toxicity LC sub 50 = > 1000 ppm. Oral Toxicity LD sub 50 = > 500 mg/kg. Dermal Toxicity LD sub 50 = > 20 mg/kg. Inhalation Toxicity LC sub 4-hrs Rat: > 1000–2000 mg/kg. Inhalation Toxicity LC sub 4-hrs Rat: > 2–20 mg/L Moderate Hazard: Temporary or transitory injury may occur; prolonged exposure may affect the CNS. Depression of general intellectual functions, irritation or sensitization. P II or Draize > 0, ≤ 5, with no destruction of dermal tissue. Eye Irritation: Slightly to mildly irritating, reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. Oral Toxicity LD sub 50 = > 50–500 mg/kg. Dermal Toxicity LD sub 50 = > 20 mg/kg. Inhalation Toxicity LC sub 4-hrs Rat: > 0.5–2 mg/L. 3 Severe Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corneal involvement or irritation clearing in more than 21 days; may cause destruction of dermal tissue, skin burns, and necrosis. P II or Draize > 5, 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 LD sub 50 = > 1–50 mg/kg. Dermal Toxicity LD sub 50 = > 20 mg/kg. Inhalation Toxicity LC sub 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. Eye 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. Oral Toxicity LD sub 50 = ≤ 1 mg/kg. Dermal Toxicity LD sub 50 = ≤ 20 mg/kg. Inhalation Toxicity LC sub 4-hrs Rat: ≤ 0.05 mg/L.

FLAMMABILITY HAZARD: 0 Minimal Hazard: Materials that will not burn in air when exposed to a 15°C (59°F) minimum temperature. Essentially non-flammable. Solids: any material with a flash point of 93.3°C (200°F) or higher. Liquids: any material with a flash point of 21.1°C (70°F) or higher. Gases: any material with an LD sub 50 = > 10,000 ppm. Materials that result in no burn hazard or fire under emergency conditions. The production of a flammable vapor, gas or mist is no hazard. 1 Moderately Hazard: Materials that are readily capable of ignition under emergency conditions by heat, sparks, friction, electrical arcing, or contact with oxidizing materials. Use of the material at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. OSHA Class IA); and Materials that ignite spontaneously when exposed to air at a temperature of 5.4°C (13°F) or below (pyrophoric).

DEFINITION OF TERMS (Continued):

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

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 undergo decomposition without powerful oxidizing agents. Explosives: Sensitizers that are Non-Rating. Peroxides: No Rating. Pyrophorics: No Rating. Oxidizers: No rating. Unstable Substances: That will not polymerize, decompose, condense, or self-react. 1 Water Reactivity: Materials that change or degrade by reaction with water. 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 explosive gases or liquids. Explosive substances are very insensitive to collisions or shock and will not react unless colliding with a powerful oxidizer or unless colliding in the presence of an igniting source. These materials are not intentionally made to react with water. Material that may react with water under emergency conditions to produce hazardous gases or liquids. The reaction may cause severe injuries or damage to property or equipment. Unstable Substances: Materials that may decompose, make, or self-react, but only under conditions of high temperature and/or pressure and have little heat generation or explosion hazards. Substances that may readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors. 2 Water Reactivity: Materials that may have fire reactions with water. Organic Peroxides: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. Explosives: Division 1.4 explosives. Explosive substances where the explosive effects are the most important. Any material that can cause a violent explosion, or cause greater damage than an equivalent quantity of 1.4-rated explosives. Any range of material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 2:1 mixture of sodium chlorate solution with cellulose. Materials that may polymerize, decompose, or self-react, but will not have a significant heat generation or explosion hazards.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: 0 Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC sub 50 for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC sub 50 for acute inhalation toxicity greater than 200 mg/L. Materials with an LC sub 50 for acute dermal toxicity greater than 2000 mg/kg. Materials with an LC sub 50 for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. 1 Minimal Hazard: Materials 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 produce hazardous atmospheres in air under almost all ambient temperatures or, under emergency conditions, can cause temporary incapacitation or heat stroke. Eye Irritation: Corrosive, severe and permanent ocular damage. Skin Irritation: Severe and permanent skin damage. Skin Sensitization: Minimal effects clearing in < 24 hours. Lung Irritation: Severe and permanent lung damage. Lung Sensitization: Scarring of lung tissue.

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DEFINITION OF TERMS (Continued):

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

REPRESENTATIVE DIAMETER:
A measure of the size of a particle or droplet.

IMS:
Integrated management system.

TLC:
Total lung capacity.

TLV:
Threshold limit value.

NTP:
National Toxicology Program.

TLD:
Total ionization dose.

LD:
Lethal dose.

LC:
Lethal concentration.

LDLo:
Lethal dose for acute oral toxicity.

LCLo:
Lethal concentration for acute oral toxicity.

LDHi:
Lethal dose for acute intraperitoneal toxicity.

LCHi:
Lethal concentration for acute intraperitoneal toxicity.

LDLoi:
Lethal dose for acute intramuscular toxicity.

LCHoi:
Lethal concentration for acute intramuscular toxicity.

LDLoi:
Lethal dose for acute intravenous toxicity.

LCHoi:
Lethal concentration for acute intravenous toxicity.

LDLoi:
Lethal dose for acute subcutaneous toxicity.

LCHoi:
Lethal concentration for acute subcutaneous toxicity.

LDLoi:
Lethal dose for acute dermal toxicity.

LCHoi:
Lethal concentration for acute dermal toxicity.

LDLoi:
Lethal dose for acute inhalation toxicity.

LCHoi:
Lethal concentration for acute inhalation toxicity.

INSTABILITY HAZARD:
0 Materials that in themselves are normally stable, even under fire conditions.
1 Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1 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) at or above 0.01 W/mL and below 10 W/mL. 2 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) at or above 10 W/mL and below 100 W/mL. 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:
1 Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. 1 Materials that must be preheated for ignition to occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the Method for Testing for Sustained Combustibility, per 49 CFR 173, Appendix H of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations (current edition) and the related Manual of Tests and Criteria (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water ratio of 95%, or by weight. Liquids and solids that, under emergency conditions, can form explosive mixtures with air and are readily dispersed in air. Liquids and solids, or combustible gases, that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1 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) at or above 0.01 W/mL and below 10 W/mL. 2 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) at or above 10 W/mL and below 100 W/mL. 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 OF SOLID MATERIALS:
Most ordinary solid materials are not flammable or will refuse to burn when exposed to a temperature of 816°C (1500°F). 1 Materials that will burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. 1 Materials that must be preheated for ignition to occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the Method for Testing for Sustained Combustibility, per 49 CFR 173, Appendix H of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations (current edition) and the related Manual of Tests and Criteria (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water ratio of 95%, or by weight. Liquids and solids that, under emergency conditions, can form explosive mixtures with air and are readily dispersed in air. Liquids and solids, or combustible gases, that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1 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) at or above 0.01 W/mL and below 10 W/mL. 2 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) at or above 10 W/mL and below 100 W/mL. 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.

TOXICOLOGICAL 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. LDLo: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LCLo: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts per million of part of air or water. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose to cause a symptom. TLDLo: Lowest concentration to cause a symptom. TDCLo: Lowest concentration to cause a chronic effect. TLDBo: Lowest concentration to cause an observable, or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-68.5°F) that cause frostbite and irreversible tissue damage. Materials with an LC50 for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. 4 Materials that, under emergency conditions, can be lethal. Gases with an LC50 for acute oral toxicity greater than 5 mg/kg but less than or equal to 1000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC50 for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD50 for acute oral toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials with an LD50 for acute dermal toxicity is less than or equal to 0.5 mg/L. Materials whose LD50 for acute oral toxicity is less than or equal to 5 mg/kg.

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<tr>
<th>Date</th>
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<td>Up-date to include European and Global Harmonization Standard compliance and classification.</td>
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