1. PRODUCT IDENTIFICATION

**TRADE NAME/MATERIAL NAME:** Animax® Cream

**DESCRIPTION:** Nystatin, Neomycin Sulfate, Thiostrepton, and Triamcinolone Acetonide Cream

**NDC #:** 0462-0123-15; 0462-0123-75

**CHEMICAL NAME (for active ingredient):** Nystatin/Neomycin Sulfate/Thiostrepton/Triamcinolone Acetonide

**CHEMICAL FAMILY (for active ingredient):** Antifungal Antibiotic/ Aminoglycoside Antibiotic/ Oligopeptide Antibiotic/Corticosteroid

**HOW SUPPLIED:** Cream

**FORMULA (for active ingredient):** C_{47}H_{75}NO_{17}/C_{23}H_{46}N_{6}O_{13}•3H_{2}O/6

**PRODUCT USE:** Pharmaceutical for Animal Use

**SUPPLIER/MANUFACTURER’S NAME:** NYCOMED US INC.

**ADDRESS:** 60 Baylis Road
Melville, NY 11747

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

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

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

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triamcinolone Acetonide</td>
<td>76-25-5</td>
<td>0.10%</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>0.25%</td>
</tr>
<tr>
<td>Thiostrepton</td>
<td>1393-48-2</td>
<td>2500 Units</td>
</tr>
<tr>
<td>Nystatin</td>
<td>1400-61-9</td>
<td>100,000 Units</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Ethylenediamine</td>
<td>107-15-3</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>13463-67-7</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Citric Acid</td>
<td>77-92-9</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Glyceryl Monostearate</td>
<td>123-94-4</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Polyethylene Glycol 400 Monostearate</td>
<td>9004-99-3</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Ceteareth-20</td>
<td>68439-49-6</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

2. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW: Product Description:** This product is a yellow to tan cream with a faint waxy 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 the active ingredients, Nystatin, Neomycin Sulfate, Thiostrepton, and Triamcinolone Acetonide, Aminoglycosides, or any other components may experience allergic reactions to this product. Allergic reactions may be severe and can be life-threatening in certain individuals. Nystatin may cause adverse reproductive effects, based on experimental data. Repeated skin exposure to Corticosteroids (such as Triamcinolone Acetonide) may cause adverse reproductive effects, based on animal data. **Flammability Hazards:** If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, sulfur oxides, 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 (Continued)

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>50-70-4</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>White Petroleum</td>
<td>8009-03-8</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Cetearyl Alcohol</td>
<td>67762-27-0</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Water and other components. Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The remaining components do not contribute any significant additional hazards. Balance

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

4 FIRST-AID MEASURES

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

SKIN EXPOSURE:  If adverse skin effects occur, discontinue use. Seek medical attention.

EYE EXPOSURE:  If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION:  If vapors from 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, viral diseases of the cornea, mycobacterial infections, and fungal diseases may be aggravated by repeated exposures 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:  Not established.

AUTOIGNITION TEMPERATURE:  Not established.

FLAMMABLE LIMITS (in air by volume, %):

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower (LEL)</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Upper (UEL)</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Spray</td>
<td>OK</td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>OK</td>
</tr>
<tr>
<td>Foam</td>
<td>OK</td>
</tr>
<tr>
<td>Dry Chemical</td>
<td>OK</td>
</tr>
<tr>
<td>Halon</td>
<td>OK</td>
</tr>
<tr>
<td>Other</td>
<td>Any &quot;ABC&quot; Class</td>
</tr>
</tbody>
</table>

FIRE EXTINGUISHING MATERIALS NOT TO BE USED:  None known.

UNUSUAL FIRE AND EXPLOSION HAZARDS:  Aminoglycosides can cause allergic anaphylactoid reactions by skin contact, and so this product poses a hazard to firefighters. If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, sulfur oxides, and hydrogen fluoride).


Explosion Sensitivity to Static Discharge:  Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES:  Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.
6. ACCIDENTAL RELEASE MEASURES

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

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

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

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

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 Federal, State, and local procedures. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

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

EXPOSURE LIMITS/GUIDELINES:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>ACGIH-TLV</th>
<th>OSHA-PELs</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
</tr>
<tr>
<td>Triamcinolone Acetonide</td>
<td>76-25-5</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Thiostrepton</td>
<td>1393-48-2</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Nystatin</td>
<td>1400-61-9</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Ethylenediamine</td>
<td>107-15-3</td>
<td>10 (skin)</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>NE</td>
</tr>
</tbody>
</table>

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

ANIMAX® CREAM MSDS

EFFECTIVE DATE: AUGUST 15, 2008

PAGE 3 OF 13
8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES (continued):

<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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>STEL</td>
<td>TWA</td>
<td>STEL</td>
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<tr>
<td></td>
<td></td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
<td>mg/m³</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>13463-67-7</td>
<td>10</td>
<td>NE</td>
<td>15 (total dust)</td>
<td>10 (vacated 1989 PEL)</td>
<td>NE</td>
</tr>
<tr>
<td>Citric Acid</td>
<td>77-92-9</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Glyceryl Monostearate (Exposure limits are for Stearates)</td>
<td>123-94-4</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Polyoxyethylene Glycol 400 Monostearate (Exposure limits are for Stearates)</td>
<td>9004-99-3</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Ceteareth-20</td>
<td>68439-49-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>50-70-4</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Propylene Glycol</td>
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<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>White Petrolatum</td>
<td>8009-03-8</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Cetearyl Alcohol</td>
<td>67762-27-0</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

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

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07). Please reference applicable regulations and standards for relevant details.

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


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

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

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: 100°C (212°F)
EVAPORATION RATE (nBuAc = 1): 0.02
FREEZING/MELTING POINT: Approx. 60°C (140°F)
SOLUBILITY IN WATER: Partially soluble.
SPECIFIC GRAVITY (water = 1): 0.99
pH: Approx. 6.5

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
APPEARANCE AND COLOR: This product is a yellow to tan cream with a faint waxy odor.

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

10. STABILITY and REACTIVITY

STABILITY: This product is stable.
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.
Nycomed US Inc.

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. Due to the presence of Methylparaben and Ethylenediamine, this product may cause respiratory sensitization in susceptible individuals; subsequent exposure to very small amounts may cause an asthma-like reaction in persons who have been sensitized. Sensitized persons may also have fever, headache, and general feelings of bodily discomfort. Reactions may occur in sensitized people immediately after exposure to Ethylenediamine, several hours after exposure, or both.

CONTACT WITH SKIN or EYES: Skin contact may cause burning sensation, stinging, pricking, itching, and tingling. Due the presence of Methylparaben and Ethylenediamine, skin contact may cause an allergic reaction in sensitive individuals; subsequent exposure to very small amounts may cause an allergic reaction once sensitized, with symptoms of redness, itching, welts and irritation. Some people sensitized to Ethylenediamine have cross-reacted to another aliphatic polyamine, TETA (triethylenetetramine) even though not previously exposed to TETA. 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. Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis. This is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Eye contact can cause temporary blurred vision and, in sensitive individuals and a failure to heal. Due to the presence of Ethylenediamine, eye contact with this product may cause a visual disturbance commonly known as "blue haze" or "halo vision". After about 1-3 hours of exposure, vision becomes foggy or blurred, objects may appear blurry, and there may be halos around lights. No eye discomfort or pain may be experienced. The effect normally clears up within a day and causes no permanent injury.

SKIN ABSORPTION: Neomycin 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. The Triamcinolone Acetonide component of this product can be absorbed through intact skin. Symptoms of chronic overexposure 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. The Ethylenediamine component of this product can be absorbed via intact skin. Absorption of Ethylenediamine through the unbroken skin can cause toxic effects. If a large area of skin is involved, symptoms can include increased heart rate, reduced red blood cell count, fever, cough, abdominal cramps, diarrhea, and blackish vomiting.

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 may include those described for "General Toxicity Information".

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HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

| HEALTH HAZARD (BLUE) | 2* |
| FLAMMABILITY HAZARD (RED) | 0 |
| PHYSICAL HAZARD (YELLOW) | 0 |

PROTECTIVE EQUIPMENT

<table>
<thead>
<tr>
<th>EYES</th>
<th>RESPIRATORY</th>
<th>HANDS</th>
<th>BODY</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEE SECTION II</td>
<td>SEE SECTION II</td>
<td>SEE SECTION II</td>
<td></td>
</tr>
</tbody>
</table>

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard
11. TOXICOLOGICAL INFORMATION (Continued)

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing the active ingredients, Nystatin, Neomycin Sulfate, Thiostrepton, and Triamcinolone Acetonide, Aminoglycosides, or any other components may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following:

For Males and Females: Persons using the product in therapeutic doses may experience burning, itching, irritation, dryness, inflammation of hair follicles, excessive growth of hair, acne-form eruptions, diminished pigmentation, dermatis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, skin atrophy, striae, and pricky heat, intraocular pressure with possible development of glaucoma, optic nerve damage, posterior subcapsular cataract formation, delayed wound healing, secondary fungal infection, and secondary bacterial infection

IRRITANT 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. Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis. Rarely, the Cetearly Alcohol component of this product can cause allergic skin reaction with hives. Due to the presence of several known and potential skin and respiratory sensitizers, susceptible persons may experience allergic reaction.

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 be harmful. Although unlikely, inhalation can irritate the respiratory system. Eye contact can cause temporary blurred vision, and, in sensitive individuals, a failure to heal.

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. Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis. Symptoms of chronic skin absorption exposure 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.

TARGET ORGANS:

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

Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin, endocrine system, blood system, bones, pituitary-adrenal system, urinary system, cardio-vascular system.

TOXICITY DATA: The toxicity data available for the active components of this product, Nystatin, Neomycin Sulfate, Thiostrepton, and Triamcinolone Acetonide, is presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Nycomed US, Inc. for more information.

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, disturbed perceptions, anorexia (human TLo (Oral-Human) 20 µg/4 hours-continuous: Skin and Appendages: dermatitis, allergic (after topical exposure)

LD₅₀ (Oral-Mouse) > 8 g/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: Behavioral: convulsions or effect on seizure threshold

LD₅₀ (Intramuscular-Guinea Pig) > 250 mg/kg: Ear: change in acute

LD₅₀ (Intracerebral-Mouse) 32 mg/kg

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

TDLo (Intracerebral-Rat) 714.3 µg/kg: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Subcutaneous-Rat) 280 mg/kg/7 days-intermittent: 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: other Enzymes

Nystatin (continued)

TDLo (Intramuscular-Monkey) 500 mg/kg/5 days-intermittent: Ear: change in acuity, changes in cochlear structure or function; Kidney/Urinary Bladder: other changes in urine composition

TDLo (Intramuscular-Cat) 5050 mg/kg/14 weeks-intermittent: Ear: change in acuity, changes in cochlear structure or function; Kidney/Urinary Bladder: other changes in urine composition

TDLo (Intravenous-Rat) 18.5 mg/kg: female 6-22 day(s) after exposure)

TDLo (Intravenous-Rat) 30 mg/kg: female 6-15 day(s) after exposure

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

TDLo (Intravenous-Rat) 90 mg/kg/41 days-intermittent: Behavioral: food intake (animal)

TDLo (Intravenous-Rat) 55.5 mg/kg/37 days-intermittent: Behavioral: food intake (animal); Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intravenous-Rat) 87 mg/kg/37 days-intermittent: Related to Chronic Data: death

TDLo (Intravenous-Rat) 30 mg/kg/10 days-intermittent: Behavioral: food intake (animal)

TDLo (Intravenous-Rat) 18,500 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.% increased weight gain), physical

TDLo (Intravenous-Rat) 30 mg/kg: female 6-15 day(s) after conception: Reproductive: Maternal Effects: other effects

TDLo (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 developmental abnormalities; Effects on Newborn: growth statistics (e.g.% decreased weight gain)
TOXICITY DATA (continued):

Nycomed US Inc.

**TRIAMCINOLONE ACETAMIDE (continued):**

- **LDLo (Intraperitoneal-Mouse) 2 gm/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Intraperitoneal-Mouse) 250 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Intraperitoneal-Mouse) 10 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Intraperitoneal-Mouse) 1 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Intraperitoneal-Mouse) 0.05 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Intraperitoneal-Mouse) 0.005 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Intraperitoneal-Mouse) 0.001 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

**TRIAMCINOLONE ACETAMIDE (continued):**

- **LDLo (Parenteral-Mouse) 1 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

- **LDLo (Parenteral-Mouse) 0.1 mg/kg:** Behavioral: pain sensation; hematopoietic systems (including spleen and marrow); Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: endocrine system; Specific Developmental Abnormalities: respiratory system; Specific Developmental Abnormalities: craniofacial (including nose and tongue); Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: other effects to embryo; Specific Developmental Abnormalities: specific effects to embryo; Specific Developmental Abnormalities: specific effects to embryo.

**Carcinogenic Potential of Components:**

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 colorectal 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.
Carcinogenic Potential of Components (continued): 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.

Long-term animal studies have not been performed to evaluate the carcinogenic potential of the other active ingredients. The incipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

- ETHYLENEDIAMINE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); EPA-D (Not Classifiable as to Human Carcinogenicity)
- GLYCERYL MONOSTEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as Human Carcinogen);
- POLYETHYLENE GLYCOL 400 MONOSTEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as Human Carcinogen);

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: Listed below is information concerning the effects of this compound on animal or human reproductive systems.

Mutagenicity: Animal studies have not been performed to evaluate the mutagenic effects of this product. No human data are available.

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

Teratogenicity: Aminoglycoside antibiotics, such as Neomycin and Polymyxin B Sulfates, cross the placenta and may cause total, irreversible, bilateral, congenital deafness in children. Nystatin may cause adverse reproductive effects, based on experimental data. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Reproductive Toxicity: Studies have not been performed to evaluate the reproductive toxicity of this product. Long-term animal studies have not been performed to evaluate the effect on fertility of topical corticosteroids.

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

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

12. ECOLOGICAL INFORMATION

All Work Practices Must Be Aimed at Eliminating Environmental Contamination.

Environmental Stability: This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption or mobility. The following environmental data are available for the components of this product:

- CITRIC ACID: Water Solubility = 59.2% (20 °C), 84% (100 °C); Biological Oxygen Demand (BOD): 40%, 5 days; 60%, 10-20 days.
- Food Chain Concentration Potential: Very Low; Experimental Log P = -1.64
- Persistence: Can ferment on standing. Biodegrades quite rapidly. It is dangerous to aquatic life in high concentrations. Lower pH in water but does not dissociate to any great extent.
- METIL PARABEN: Water solubility = Soluble; Experimental Log P = 1.58
- NYSTATIN: Bioconcentration: An estimated BCF of 22 was calculated for Nystatin, using a water solubility of 3.6X10+2 mg/mL and a regression-derived equation. According to a classification scheme, this estimated BCF suggests the potential for bioconcentration in aquatic organisms is low provided the compound is not metabolized by the organism.
- Soil Adsorption/Mobility: The Koc of Nystatin is estimated as 170, using a water solubility of 3.6X10+2 mg/mL at 25°C and a regression-derived equation.
- Persistence and Biodegradability: If released to air, an estimated vapor pressure of 8.7X10-7 mm Hg at 25°C indicates Nystatin will exist in both the vapor and particulate phases in the atmosphere. Vapor-phase Nystatin will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 1.5 hours. Reaction with ozone is estimated to be 2.6 hours. Particulate-phase Nystatin will be removed from the atmosphere by wet or dry deposition. Nystatin may be susceptible to direct photolysis by sunlight. If released to soil, Nystatin is expected to have moderate mobility based upon an estimated Koc of 170. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 2.0X10-7 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/L. Numerous screening studies using wastewater or sewage inoculum as seed, suggests that Nystatin is expected to have very high mobility in soil. Volatilization from dry soil surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.
- PROPYLENE GLYCOL: Bioconcentration: An estimated BCF of 3 was calculated for Propylene Glycol, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.
- Soil Adsorption/Mobility: The Koc of Propylene Glycol is expected to be as 8, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that Propylene Glycol is expected to have very high mobility in soil.
- Persistence and Biodegradability: Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that Propylene Glycol is expected to have very high mobility in soil. Volatilization of Propylene Glycol from moist soil surfaces is not expected to be an important fate process given an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/L. Numerous screening studies using wastewater or sewage inoculum as seed, suggests that Propylene Glycol will be degraded readily under aqueous environments. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Propylene Glycol, which has a vapor pressure of 0.13 mmHg at 25°C, is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase Propylene Glycol is expected to exist in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 32 hours, calculated from its rate constant of 1.2X10-11 cu cm/molecule-sec at 25°C.
- SORBITOL: Terrestrial Fate: Based on a classification scheme, an estimated Koc value of 2, determined from a log Kow of -2.2 and a regression-derived equation, indicates that Sorbitol is expected to have very high mobility in soil. Volatilization of Sorbitol from moist soil surfaces is not expected to be an important fate process given an estimated Henry's Law constant of 7.3X10-13 atm-cu m/mole, using a fragment constant estimation method. Sorbitol is not expected to volatilize from dry soil surfaces based upon an estimated vapor pressure of 4.9X10-9 mm Hg, determined from a fragment constant method. Sorbitol is a simple sugar alcohol and should be readily biodegraded in the environment.
12. ECOLOGICAL INFORMATION (Continued)

ENVIRONMENTAL STABILITY (continued):

Sorbitol (continued):

Aquatic Fate: Based on a classification scheme, an estimated log Koc value of 2, determined from a log Kow of -2.2 and a regression-derived equation, indicates that Sorbitol is not expected to adsorb to suspended solids and sediment in water. Volatilization from water surfaces is not expected based upon an estimated Henry's Law constant of 7.3X10-13 atm-cu m/mole, developed using a fragment constant estimation method. According to a classification scheme, an estimated BCF of 1, determined from its log Kow and a regression-derived equations, suggests the potential for bioconcentration in aquatic organisms is low. Sorbitol is a simple sugar alcohol and should be readily biodegraded in the environment.

Atmospheric Fate: According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Sorbitol, which has an estimated vapor pressure of 4.3X10-9 mm Hg at 25°C, is expected to exist in the particulate phase in the ambient atmosphere. Particulate-phase Sorbitol may be removed from the air by wet and dry deposition.

Bioconcentration: An estimated BCF of 1 was calculated for Sorbitol, using a log Kow of -2.2 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

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

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

CITRIC ACID:

EC50 (Pseudomonas putida bacteria) 16 hours > 10,000 mg/L
EC10 (Microcystis aeruginosa algae) 8 days < 80 mg/L
EC10 (Scenedesmus quadricauda green algae) 7 days > 640 mg/L
EC10 (Entoiothion sulcatum protozoa) 72 hours > 485 mg/L
EC10 (Uronema parodozi Chatton-Lwoff protozoa) > 622 mg/L
LD50 (Daphnia magna giant water flea) > 80 mg/L long-term exposure in soft water
LD50 (goldfish) > 625 mg/L long-term exposure in hard water
LD10 (Daphnia magna giant water flea) > 120 mg/L long-term exposure in soft water
LD10 (goldfish) > 625 mg/L long-term exposure in hard water
TLM (shore crab) 48 hours = 160 ppm salt water

PROPYLENE GLYCOL:

EC50 (Photobacterium phosphoreum, bacteria) 30 minutes = 26,800 mg/L

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: Components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act, as follows:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>SARA 302 (40 CFR 355, Appendix A)</th>
<th>SARA 304 (40 CFR Table 302.4)</th>
<th>SARA 313 (40 CFR 372.65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylenediamine</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

U.S. SARA SECTION 302 EXTREMELY HAZARDOUS THRESHOLD PLANNING QUANTITY (TPQ): Ethylenediamine = 10,000 lb (4540 kg)

U.S. SARA SECTION 304 EXTREMELY HAZARDOUS REPORTABLE QUANTITY (RQ): Ethylenediamine = 10,000 lb (4540 kg)

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Ethylenediamine = 5,000 lb (2270 kg)

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.

U.S. EPA CLEAN AIR ACT, SECTION 112 (r), RISK MANAGEMENT PROGRAMS FOR CHEMICAL ACCIDENTAL RELEASE (40 CFR PART 68): Threshold Planning Quantity (TPQ): Ethylenediamine = 20,000 lb (9080 kg)

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

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

CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOLS: Not applicable.

16. OTHER INFORMATION

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

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.
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DATE OF PRINTING: August 26, 2008
A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

**CAS #:** This is the Chemical Abstract Service Number that uniquely identifies each constituent.

**EXPOSURE LIMITS IN AIR:**
- **CEILING LEVEL:** The concentration that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded during any part of the workday.
- **DISSOLVED GAS:** The percent, by volume, of gas present in a liquid.
- **DGF MAK Germ Cell Mutagen Categories:**
  - 1: Germ cell mutagens that have been shown to produce genetic effects in mammalian germ cells.
  - 2: Germ cell mutagens that have been shown to induce genotoxic effects in germ cells of human or animal species.
  - 3: Germ cell mutagens that have been shown to induce genotoxic effects in germ cells of non-human test animals but do not produce genetic effects in mammalian germ cells.
  - 4: Germ cell mutagens that have been shown to induce genotoxic effects in germ cells of non-human test animals and do not produce genetic effects in mammalian germ cells.

**DEFINITION OF TERMS**

**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):**

**HEALTH HAZARD:** The potential for an injury to be caused by exposure to the substance or material.

**RATING:**
- **1:** Minimal Hazard: No rating.
- **2:** Moderate Hazard: Moderate irritant; sensitive. PiI or Draize > 5.0 mg/kg.
- **3:** Severe Hazard: Major irritant likely unless prompt action is taken; high level of toxicity; corrosive; eye irritation alone.
- **4:** Extreme Hazard: Severe irritant and/or corrosive; possible chemical flash fire hazards; major injury likely unless prompt action is taken.

**PHYSICAL HAZARD:**
- **0:** Water Reactivity: Materials that do not react with water.
- **1:** Oxidizers: Materials that oxidize spontaneously at ambient temperature.
- **2:** Explosives: Materials that can become unstable at high temperatures or pressures.
- **3:** Flammable Liquids: Materials that ignite spontaneously when exposed to air at a temperature of 1500°F (815.5°C).

**EFFECTIVE DATE: AUGUST 15, 2008**

**ANIMAX CREAM MSDS PAGE 11 OF 13**
HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

**PHYSICAL HAZARD (continued):**

1 (continued) Unstable Reactives: Substances that may decompose, condense, or self-react, but only under conditions of high temperature and/or pressure, and have a flash point below 22.8°C (73°F) and/or equal to 200 ppm or less.

2 Reactivity: Materials that may react violently 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 largely confined to the package and do not cause damage on an appreciable scale or range. An external fire may not cause virtually instantaneous explosion of almost the entire contents of the package. Compressed Gases: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) (500 psi). Pyrophorics: No Rating. Oxidizers: Packing Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2.3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chloride solution (40%) + cellulose mixture and the criteria for Packing Group I are not met. Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but under all ambient temperature and/or pressure conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC₅₀ for acute dermal toxicity greater than 2000 mg/kg. Materials with an LC₅₀ for acute inhalation toxicity greater than or equal to 10 mg/L. Materials with an LD₅₀ acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the skin. Cyanogenic gases that cause frothbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°F (-46.5°C) that cause frothbite and irreversible tissue damage. Materials with an LD₅₀ for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. Materials that, under emergency conditions, can be lethal. Gases with an LC₅₀ for acute inhalation toxicity less than or equal to 1,000 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 3,000 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. Gases and vapors with an LD₅₀ for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg.

3 Health HAZARD (continued):

Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC₅₀ for acute inhalation toxicity greater than or equal to 5,000 ppm or greater than 0.5 mg/L but less than or equal to 5,000 ppm 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 3,000 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. Gases and vapors with an LD₅₀ for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials with an LD₅₀ for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 1000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD₅₀ for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD₅₀ for acute oral toxicity is less than or equal to 5 mg/kg. FLAMMABILITY HAZARD: 0 Materials that will not burn under typical fire conditions. Solids that are combustible but not flammable (e.g. rubber, masonry, 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 before ignition can occur. Materials in this H category can sustain a flash if considered mixtures, or will sustain a flash 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 III B 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 or the UN Recommendations on the Transport of Dangerous Goods, Model Regulations (with modifications to 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 non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92. Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 2 Materials that may be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperature or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and IIIA liquids). Solid materials with a flash point in the form of powders or fine dusts having a representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, wool, asphalt. Solids and semisolids having a flash point less than 22.8°C (73°F). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 3 Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IIB and IC liquids). Partially or completely liquid materials in the form of overlapping layers that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 4 Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IIB and IC liquids). Materials that contain less than 10% by volume of a flammable or combustible solvent in esters that can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh) that will burn with extreme rapidity, usually by reason of self-ignition of the dust or from an external source. Oxidizing substances that will burn rapidly but do not form explosive mixtures with air. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 4 Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or under high ambient pressure or high ambient temperature and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 78.8°C (173°F) (i.e. Class IIA liquids). Flammable or combustible dusts that will burn readily when exposed to air. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.
DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD: 0 Materials that in themselves are normally stable, even under fire conditions. 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 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. 5 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 100 W/mL and below 1000 W/mL. 6 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) at or above 100 W/mL and below 1000 W/mL. 7 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 100 W/mL and below 1000 W/mL. 8 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) at or above 100 W/mL and below 1000 W/mL. 9 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 100 W/mL and below 1000 W/mL. 10 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) at or above 100 W/mL and below 1000 W/mL. 11 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 100 W/mL and below 1000 W/mL. 12 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) at or above 100 W/mL and below 1000 W/mL.

FLAMMABILITY LIMITS IN AIR:

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

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. LD50: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC50: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/m3: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDL0: Lowest dose to cause a symptom. TCL0: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TC0, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects. Cancer Information: IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. Other Information: BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLM: Median threshold limit. Log Kow or Log Koc: Coefficient of Oil/Water Distribution is used to assess a substance’s behavior in the environment.

REGULATORY INFORMATION:

U.S.:

EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material’s package label.

CANADA:

WHMIS: Canadian Workplace Hazardous Materials Information System. TC; Transport Canada. DSL/NDSL: Canadian Domestic/Non-Domestic Substances List.