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

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Animax® Ointment

DESCRIPTION: Nystatin, Neomycin Sulfate, Thioestrepton, and Triamcinolone Acetonide Ointment

NDC #: 0168-0122-15; 0168-0122-24; 0168-0122-30; 0168-0122-75

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

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

HOW SUPPLIED: Ointment

FORMULA (for active ingredient): C_{47}H_{75}NO_{17}/C_{23}H_{46}N_{6}O_{13}\times3H_{2}O/S/C_{72}H_{85}N_{19}O_{18}S_{5}/ C_{24}H_{31}FO_{6}

PRODUCT USE: Pharmaceutical for Animal Use

SUPPLIER/MANUFACTURER'S NAME: NYCOMED US INC.

ADDRESS: 60 Baylis Road
Melville, NY 11747

BUSINESS PHONE (U.S./Canada/Puerto Rico): 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

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

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Product Description: This product is a yellow to tan ointment 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, Thioestrepton, 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: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, 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

<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>Thioestrepton</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>A C Polyethylene 3A</td>
<td>9002-88-4</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8012-95-1</td>
<td>Balance</td>
</tr>
</tbody>
</table>

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

4 FIRST-AID MEASURES

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

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, %):

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

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

<table>
<thead>
<tr>
<th>Water Spray</th>
<th>Carbon Dioxide</th>
<th>Foam</th>
<th>Dry Chemical</th>
<th>Halon</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>OK</td>
<td>OK</td>
<td>OK</td>
<td>OK</td>
<td>OK</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. This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, 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 bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.
6. ACCIDENTAL RELEASE MEASURES (Continued)

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

PART III How can I prevent hazardous situations from occurring?

7. HANDLING and USE

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

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

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

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

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

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

EXPOSURE LIMITS/GUIDELINES:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>ACGIH-TLVs</td>
<td>OSHA-PELs</td>
<td>NIOSH-RELs</td>
<td>NIOSH</td>
<td>OTHER</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³ STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
</tr>
<tr>
<td>Triamcinolone Acetate</td>
<td>76-25-5</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
</tr>
<tr>
<td>Neomycin Sulfate</td>
<td>1405-10-3</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
</tr>
<tr>
<td>Thiostrepton</td>
<td>1393-48-2</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
</tr>
<tr>
<td>Nystatin</td>
<td>1400-61-9</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
</tr>
<tr>
<td>A C Polyethylene 3A</td>
<td>9002-88-4</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8012-95-1</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE NE</td>
<td>NE 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOILING POINT</td>
<td>150°C (302°F)</td>
</tr>
<tr>
<td>FREEZING/MELTING POINT</td>
<td>Not established.</td>
</tr>
<tr>
<td>EVAPORATION RATE (nBuAc = 1)</td>
<td>0</td>
</tr>
<tr>
<td>SOLUBILITY IN WATER</td>
<td>Partially soluble.</td>
</tr>
<tr>
<td>VAPOR PRESSURE (air = 1)</td>
<td>Not established.</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY A 20°C (water = 1)</td>
<td>0.87</td>
</tr>
<tr>
<td>ODOR THRESHOLD</td>
<td>Not established.</td>
</tr>
<tr>
<td>pH</td>
<td>Not established.</td>
</tr>
<tr>
<td>COEFFICIENT WATER/OIL DISTRIBUTION</td>
<td>Not established.</td>
</tr>
</tbody>
</table>

APPEARANCE AND COLOR: This product is a yellow to tan ointment 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.

DECOMPOSITION PRODUCTS: Combustion: Carbon oxides, nitrogen oxides, sulfur oxides, 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, caustics, and other chemicals that could affect its performance should be avoided.

HAZARDOUS POLYMERIZATION: Will not occur.

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

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

11. TOXICOLOGICAL INFORMATION

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

INHALATION: Although unlikely due to form of product, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Skin contact may cause burning sensation, stinging, pricking, itching, and tingling. Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, anaphylaxis, 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, a failure to heal.

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.

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.
### 11. TOXICOLOGICAL INFORMATION (Continued)

**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.”

**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, dermatitis 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

**IRRITANCY OF PRODUCT:** This product may mildly to moderately irritate contaminated tissue.

**SENSITIZATION OF PRODUCT:** Aminoglycosides have a low order of toxicity when applied topically; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals. Corticosteroids (such as Triamcinolone Acetonide) may cause allergic contact dermatitis.

**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:**

NEOMYCIN SULFATE (continued):

<table>
<thead>
<tr>
<th>DLo</th>
<th>Route</th>
<th>Species</th>
<th>Gender</th>
<th>Data</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Oral-Mouse) &gt; 8 g/kg</td>
<td></td>
<td></td>
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<tr>
<td>LD50 (Subcutaneous-Rat) 200 mg/kg</td>
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<tr>
<td>LD50 (Intraperitoneal-Mouse) 305 mg/kg</td>
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<tr>
<td>LD50 (Intravenous-Mouse) 17,400 µg/kg</td>
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</tr>
<tr>
<td>LD50 (Intramuscular-Mouse) 142 mg/kg</td>
<td>Behavioral: convulsions or effect on seizure threshold</td>
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</tr>
<tr>
<td>LD50 (Intramuscular-Guinea Pig) &gt; 250 mg/kg: Ear; change in acuity</td>
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<tr>
<td>LD50 (Intracerebral-Mouse) 32 mg/kg</td>
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<tr>
<td>TDLo (Intraspinal-Rat) 36.88 µg/kg: Behavioral: analgesia</td>
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<tr>
<td>TDLo (Intrathecral-Rat) 714.3 µg/kg: Blood; changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Neurotransmitters or modulators (putative): catecholamine levels in CNS</td>
<td></td>
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<tr>
<td>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: phosphatases</td>
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</tr>
</tbody>
</table>

**Nystatin (continued):**

<table>
<thead>
<tr>
<th>DLo</th>
<th>Route</th>
<th>Species</th>
<th>Gender</th>
<th>Data</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Oral-Rat) 10 g/kg</td>
<td></td>
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</tr>
<tr>
<td>LD50 (Oral-Mouse) 8 g/kg</td>
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<td></td>
</tr>
<tr>
<td>LD50 (Intraperitoneal-Rat) 24,305 µg/kg</td>
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</tr>
<tr>
<td>LD50 (Intraperitoneal-Mouse) 4,400 µg/kg</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>LD50 (Subcutaneous-Mouse) 120 µg/kg</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>LD50 (Intravenous-Mouse) 3 mg/kg</td>
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</tr>
<tr>
<td>TLo (Inhalation-Rat) 5 mg/ml/4 hours/17 weeks-intermittent: Immunological Including Allergic: hypersensitivity delayed</td>
<td></td>
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</tr>
<tr>
<td>TLo (Inhalation-Rat) 40 mg/ml/24 hours/10 days-continuous: Immunological Including Allergic: decrease in humoral immune response; Biochemical: Metabolism (Intermediary): Plasma proteins not involving coagulation</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
TOXICITY DATA (continued):

NYSTAIN (continued):

TDL0 (Intravenous-Rat) 30 mg/kg; female 6-15 days after conception: Reproductive: Maternal Effects: other systemic changes; other developmental abnormalities: Effects on Newborn: growth statistics (e.g., reduced weight gain)

TDL0 (Intraspinous-Monkey) 50 mg/kg: female 9 days after conception: Reproductive; Effects on Endometrium: other changes; Blood: leukopenia

TDL0 (Implant-Mouse) 6500 µg/kg: female 6-18 days after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue); Other: effects on embryos and fetuses

TDL0 (Implant-Mouse) 5 mg/kg: female 11 days 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)

TDL0 (Implant-Mouse) 2 mg/kg; female 23-31 days after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDL0 (Implant-Monkey) 50 mg/kg: female 23-31 days after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), musculoskeletal system, blood and lymphatic systems (including spleen and marrow)

TDL0 (Implant-Monkey) 60 mg/kg; female 41-44 days after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDL0 (Implant-Monkey) 6 mg/kg; female 41-44 days after conception: Reproductive: Effects on Endometrium or Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death

TDL0 (Implant-Monkey) 3 mg/kg; female 63-65 days after conception: Reproductive: Specific Developmental Abnormalities: respiratory system

TDL0 (Implant-Hamster) 500 µg/kg; female 9 days 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; Reproductive, other developmental abnormalities

TDL0 (Implant-Hamster) 100 µg/kg; female 11 days after conception: Reproductive: Specific Developmental Abnormalities: endocrine system; Effects on Newborn: biochemical and metabolic

TDL0 (Implant-Mouse) 650 mg/kg; female 6-18 days after conception: Reproductive: Fertility: pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)

Unscheduled DNA Synthesis (Human Cells) 1 nmol/L

DNA Inhibition (Human Cells) 10 nmol/L

Mutation Test Systems Not Otherwise Specified (Skin-Human) 5000 ppm

DNA Inhibition (Mouse Cells) 1 nmol/L

DNA Inhibition (Mouse-Leukocyte) 10 nmol/L

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 colon adenocarcinomas than did those in the control group.
11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL OF COMPONENTS (continued): 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.

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

MINERAL OIL: IARC-3 (Not Classifiable as to Carcinogenicity to 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: 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 teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

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

NYSTATIN: Bioconcentration: An estimated BCF of 22 was calculated for Nystatin, using a water solubility of 3.60X10+2 mg/L and a regression-derived equation. According to a classification scheme, this 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 3.60X10+2 mg/L at 25°C and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that Nystatin is expected to have moderate mobility in soil.

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 also expected to occur; the half-life for this reaction 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 2.0X107 atm-cu m/mole. Nystatin is not expected to volatilize from dry soil surfaces based upon its vapor pressure. A 4% degradation in 28 days using the Closed Bottle test indicates that biodegradation is not an important environmental fate process. If released into water, Nystatin is expected to adsorb slightly to suspended solids and sediment based upon the estimated Koc. Volatilization from water 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.

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

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

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

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

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.
13. DISPOSAL CONSIDERATIONS (Continued)

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.

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

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

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

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

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE SEVERE ANAPHYLACTIC ALLERGIC REACTION, WHICH MAY BE LIFE-THREATNING. 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.

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A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

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

### HEALTH HAZARD (continued):

- **Eye Irritation:** Corrosive, irreversible destruction of ocular tissue; corneal irritation or irritation persisting for more than 21 days Oral Toxicity LD₅₀ Rat or Rabbit: > 20–200 mg/kg InhalaTion Toxicity LC₅₀ 4-hrs Rat: > 0.05–0.5 mg/L 3 Severe Hazard: Major or permanent damage to skin and mucous membranes; severe irritation may result from contact. Skin Irritation: Not appropriate. Do not rate as a 4, based on skin irritation alone. Eye Irritation: Not appropriate. Do not rate as a 4, based on eye irritation alone. Oral Toxicity LD₅₀ Rat or Rabbit: > 20 mg/kg InhalaTion Toxicity LC₅₀ 4-hrs Rat: > 0.05 mg/L

### FLAMMABILITY HAZARD:

- **Minimal Hazard:** Materials that will not burn in air when exposed to a temperature of 815.8°C (1500°F) for a period of 5 minutes or less. There are no applicable criteria for Packing Group I and II are not met. Unstable Reactives: Substances that may decompose, condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. 2 Water Reactivity: Materials that may react violently with water. Organic Peroxides: Materials that are normally stable, under fire conditions and will not react with water. Explosives: Substances that are non-Explosive. Compressed Gases: No Rating. Pyrophoric: No Rating. Substances that may polymerize, decompose, or self-react. 1 Water Reactivity: Materials that change or decompose upon exposure to moisture. Organic Peroxides: Materials that are normally stable, under fire conditions and will not react with water. Explosives: Substances that are non-Explosive. Pressurized and meet OSHA definition. No Rating. Pyrophoric: No Rating. Substances that may polymerize, decompose, or self-react. 1 Water Reactivity: Materials that may react violently with water. Organic Peroxides: Materials that are normally stable, under fire conditions and will not react with water. Explosives: Substances that are non-Explosive. Compressed Gases: No Rating. Pyrophoric: No Rating. Substances that may polymerize, decompose, or self-react. 1 Water Reactivity: Materials that may react violently with water. Organic Peroxides: Materials that are normally stable, under fire conditions and will not react with water. Explosives: Substances that are non-Explosive. Compressed Gases: No Rating. Pyrophoric: No Rating. Substances that may polymerize, decompose, or self-react.

### HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

- **Minimal Hazard:** No significant health risk, irritation of skin or eyes not anticipated. Skin Irritation: Essentially non-irritating. Mechanical irritation may occur. women can lead to damage of the developing organism, even when MAK and BAT Biological Tolerance Value for Working Materials) values are observed. Substances that will not polymerize, decompose, condense, or self-react. Substances that will not polymerize, decompose, condense, or self-react. Substances that will not polymerize, decompose, condense, or self-react. Explosives: Division 1.5 & 1.6 explosives. Substances that may polymerize, decompose, or self-react. Explosives: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire may cause combustion of almost the entire contents of the package. Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. Pyrophoric: No Rating. Oxidizers: Packing Group II oxidizers. Solids: any material that, in either concentration tested, exhibits a mean 

### COMPOSITION OF TERMS:

#### DEFINITION OF TERMS:

- **Materials that will rapidly or completely vaporize at room temperature.**
- **Materials that will not burn in air when exposed to a temperature of 815.8°C (1500°F) for a period of 5 minutes or less.**
- **Materials that may react violently with water.**
- **Inhalation toxicity LC₅₀ 4-hrs Rat:**
- **Inhalation toxicity LC₅₀ 4-hrs Rat:**
- **Dermal Toxicity LD₅₀ Rat or Rabbit:**
- **Eye Irritation:** Corrosive, irreversible destruction of ocular tissue; corneal irritation or irritation persisting for more than 21 days Oral Toxicity LD₅₀ Rat or Rabbit: > 20–200 mg/kg InhalaTion Toxicity LC₅₀ 4-hrs Rat: > 0.05–0.5 mg/L

### HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

- **Minimal Hazard:** No significant health risk, irritation of skin or eyes not anticipated. Skin Irritation: Essentially non-irritating. Mechanical irritation may occur. women can lead to damage of the developing organism, even when MAK and BAT Biological Tolerance Value for Working Materials) values are observed. Substances that will not polymerize, decompose, condense, or self-react. Substances that will not polymerize, decompose, condense, or self-react. Explosives: Division 1.5 & 1.6 explosives. Substances that may polymerize, decompose, or self-react. Explosives: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire may cause combustion of almost the entire contents of the package. Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. Pyrophoric: No Rating. Oxidizers: Packing Group II oxidizers. Solids: any material that, in either concentration tested, exhibits a mean
**HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):**

**FLAMMABILITY HAZARD (continued):**

**FLAMMABILITY (continued):**

- Liquids that have no fire point or boiling point less than or equal to 37.8°C (100°F) and are not combustible or non-flammable.
- Liquids that have a fire point or boiling point of 37.8°C (100°F) but no flash point.

**FIRE RATING:**

- Class I: Flammable liquids with flash points at or above 37.8°C (100°F) and below 60°C (140°F).
- Class II: Flammable liquids with flash points at or above 60°C (140°F) and below 93.4°C (200°F).
- Class IIIA: Flammable liquids with flash points at or above 93.4°C (200°F) and below 110°C (225°F).
- Class IIB: Flammable liquids with flash points at or above 110°C (225°F) and below 120°C (248°F).
- Class IIC: Flammable liquids with flash points at or above 120°C (248°F) and below 125°C (257°F).
- Class IID: Flammable liquids with flash points at or above 125°C (257°F) and below 140°C (285°F).
- Class IIIE: Flammable liquids with flash points at or above 140°C (285°F) and below 180°C (356°F).
- Class IIIF: Flammable liquids with flash points at or above 180°C (356°F).

**EXPLOSION RATING:**

- Class I: Exothermic decomposition reactions, leading to a pressure rise time of less than 2 seconds.
- Class II: Exothermic decomposition reactions, leading to a pressure rise time of 2 to 5 seconds.
- Class III: Exothermic decomposition reactions, leading to a pressure rise time of 5 to 20 seconds.
- Class IV: Exothermic decomposition reactions, leading to a pressure rise time of greater than 20 seconds.

**FLAMMABILITY LIMITS IN AIR:**

- FLAMMABLE LIMITS IN AIR:
  - Lower Flammable Limit (LFL): The lowest concentration of a flammable or combustible vapor or gas/air mixture that will ignite and burn with a stable flame. The LFL is expressed as a percentage of the volume of the gas or vapor in air.
  - Upper Flammable Limit (UFL): The highest concentration of a flammable or combustible vapor or gas/air mixture that will ignite and burn with a stable flame. The UFL is expressed as a percentage of the volume of the gas or vapor in air.

**INSTABILITY HAZARD:**

- Materials that in themselves are normally stable, but under certain conditions, can cause self-ignition or spontaneous combustion.

**FLAMMABILITY HAZARD:**

- Materials that will not burn under certain fire conditions, indicating that they do not burn in air, or are not flammable in the presence of air.

**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. This includes information on cancer, reproductive toxicity, neurotoxicity, skin sensitization, and respiratory effects. Additionally, data on the lowest observable adverse effect level (LOAEL) and no observed adverse effect level (NOAEL) are provided. These terms are used to indicate the doses at which adverse effects have been observed or not observed, respectively.

**Concentration (gases) that kills 50% of the exposed animals, ppm:**

- Concentration expressed in parts per million of air.
- Concentration expressed in weight of substance per volume of air.
- mg/L: Concentration expressed in weight of substance per volume of water.

**Additional Information:**

- BEI: Biological Effects Index.
- CACG: Carcinogenicity Biological Activity Group.
- NTP: National Toxicology Program.
- R Eternal: Registry of Toxic Effect Substances.
- WHO: World Health Organization.
DEFINITION OF TERMS (Continued)

ECOLOGICAL INFORMATION:
EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. log K(MIOS) or log K(OC): 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: