SAFETY DATA SHEETS

This SDS packet was issued with item:

078360601

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078079716 078079724 078360619 078360627 078484082

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078079708 078360585 078360593

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, REACH, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

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

TRADE NAME/MATERIAL NAME: Animax® Ointment

DESCRIPTION: Nystatin, Neomycin Sulfate, Thiostrepton, and Triamcinolone Acetonide Ointment
NDC #: 15 mL: 17033-122-15; 240 mL: 17033-133-24; 30 mL: 17033-122-30; 7.5 mL: 17033-122-75
CHEMICAL NAME (for active ingredients):
For Nystatin: (21E,23E,25E,27E,31E,33E)-20-{[(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy}-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid
For Neomycin Sulfate: 2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-*O*-(2,6-diamino-2,6-dideoxy-B-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine
For Thiostrepton: (21E,23E,25E,27E,31E,33E)-20-{[(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy}-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid
For Triamcinolone Acetonide: Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11 beta,16 alpha)-
CHEMICAL FAMILY (for active ingredients): For Nystatin: Aminoglycoside; For Neomycin Sulfate: Aminoglycoside
For Thiostrepton: Ogliopeptide; For Triamcinolone Acetonide: Corticosteroid
FORMULA (for active ingredients): For Nystatin: $C_{46}H_{83}NO_{18}$; For Neomycin Sulfate: $C_{23}H_{46}N_6O_{13}3H_2SO_4xH_2O$;
For Thiostrepton: $C_{72}H_{85}N_{19}O_{18}S_5$; For Triamcinolone Acetonide: $C_{24}H31FO_6$
HOW SUPPLIED: 7.5, 15, 30 and 240 mL tubes containing 0.25% Neomycin Sulfate, 0.1% Triamcinolone Acetonide, 100,000 units Nystatin and 2500 units Thiostrepton per mL
RELEVANT USE of the SUBSTANCE: Veterinary Drug
USES ADVISED AGAINST Not for Human Use
SUPPLIER/MANUFACTURER'S NAME: **FOUGERA PHARMACEUTICALS INC. (for Dechra)**
ADDRESS: 60 Baylis Road
Melville, NY 11747
BUSINESS PHONE/GENERAL SDS INFORMATION: 1-631-454-7677
EMERGENCY PHONE (U.S./Canada/, International): Chemtel: 1 (813) 676-1670 (24-hr)

ALL WHMIS required information is included in appropriate sections based on the GHS format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The product is also classified per all applicable EU Directives through REACH, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EMERGENCY OVERVIEW: Product Description: This product is a yellow to tan ointment with a faint waxy odor. This product is a veterinary product used in treatment of dogs and cats and is not used therapeutically in humans. The following possible health hazards information is for humans and is based on information for active ingredients when used in human health care. ***Health Hazards:*** In the workplace, exposure via eye contact may cause irritation. Prolonged skin contact may cause redness or skin discomfort. Ingestion may be harmful. Inhalation is unlikely due to viscosity. Exposure may cause acne-like eruptions, burning, dryness, excessive hair growth, infection of the skin, irritation, itching, lack of skin color, prickly heat, skin inflammation, skin loss or softening, or stretch. Chronic exposure can cause adverse effects on the immune and adrenal systems and eyes. Chronic exposure can result in increased susceptibility to infections and may exacerbate systemic fungal infections. Rare instances of anaphylactoid reactions have occurred in persons receiving corticosteroid therapy; these reactions may also occurred to susceptible individuals handling this product. Allergic reactions may be severe and can be life-threatening in certain individuals. Limited evidence of harm to the fetus, based on animal information for the active ingredients. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for information on other potential health hazards known for the active ingredients. ***Flammability Hazards:*** This product is combustible and may ignite if exposed to direct flame or if highly heated for a prolonged period. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds, including carbon and nitrogen oxides, sulfur compounds and hydrogen fluoride. ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS GHS Under U.S. OSHA & EU Classification (1272/2008 EC) Hazard Statement Codes
ACTIVE INGREDIENTS				
Neomycin Sulfate 2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-*O*-(2,6-diamino-2,6-dideoxy-B-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine	1405-10-3	215-773-1	0.025%	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Reproductive Toxicity Cat. 2, Skin Sensitization Cat. 1A, Respiratory Sensitization Cat. 1B, Skin Irritation Cat. 2, Eye Irritation Cat. 2A, STOT RE Cat. 2 Hazard Codes: H361d, H317, H334, H315, H319, H373
Triamcinolone Acetonide Pregna-1,4-diene-3,20-dione, 9-Fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis-(oxy)]-, (11β,16α)-	76-25-5	200-948-7	0.1%	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, STOT (Dermal-Multiple Organs) RE Cat. 2 Hazard Codes: H361d, H302, H315, H373
Nystatin (21E,23E,25E,27E,31E,33E)-20-{[(3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy}-4,6,8,11,12,16,18,36-octahydroxy-35,37,38-trimethyl-2,14-dioxo-1-oxacyclooctatriaconta-21,23,25,27,31,33-hexaene-17-carboxylic acid	1400-61-9	215-749-0	100,000 units	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Reproductive Toxicity Cat. 2, Aquatic Acute Toxicity Cat. 1 Hazard Codes: H361d, H400
Thiostrepton N-{3-[(3-Amino-3-oxo-1-propen-2-yl)amino]-3-oxo-1-propen-2-yl}-2-[37-sec-butyl-18-(2,3-dihydroxy-2-butanyl)-11-ethylidene-59-hydroxy-8,31-bis(1-hydroxyethyl)-26,40,46-trimethyl-43-methylene-6,9,16,23,28,38,41,44,47-nonaoxo-27-oxa-3,13,20,56-tetrathia-7,10,17,24,36,39,42,45,48,52,58,61,62,63,64-pentadecaazanonacyclo[23.23.9.3^{29,35}.1^{2,5}.1^{12,15}.1^{19,22}.1^{54,57}.0^{1,53}.0^{32,60}]tetrahexaconta-2(64),4,12(63),19(62),21,29,31,33,51,54,57,6	1393-48-2	215-734-9	2500 units	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 4 Hazard Codes: H302
EXCIPIENTS:				
Ethylene Homopolymer	9002-88-4	Not Listed	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Mineral Oil	8042-47-5	232-455-8	Balance	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Aspiration Hazard Cat. 1 Hazard Codes: H304

See Section 16 for full classification information of product and components.

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

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: rescuers should wear adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, if necessary. Remove victim(s) to fresh air, as quickly as possible. Take copy of product label and SDS to physician or other health professional with victim(s).

Skin Exposure: If adverse skin effects occur, seek medical attention.

Eye Exposure: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Inhalation: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

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

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

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

4 FIRST-AID MEASURES (Continued)

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. No specific antidote is available for this product. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %): Not applicable. Not applicable.

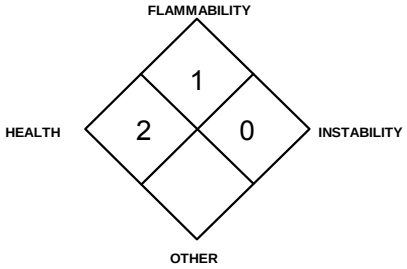
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product is combustible. If heated to high temperatures for a prolonged period it may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic gases (e.g., carbon and nitrogen oxides, sulfur compounds and hydrogen fluoride).

Explosion Sensitivity to Mechanical Impact or Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

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

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product. Spills may be slippery.

PROTECTIVE EQUIPMENT:

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

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills: The product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Large Spills: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

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

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

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

7. HANDLING and USE (Continued)

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a veterinary drug.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Wipe equipment down with damp sponge or polypad. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Collect all rinsates and dispose of according to applicable waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Workplace Exposure Limits/Control Parameters:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Neomycin Sulfate	1405-10-3	NE	NE	NE	NE	NE	NE	NE	NE
Nystatin	1400-61-9	NE	NE	NE	NE	NE	NE	NE	NE
Thiostrepton	1393-48-2	NE	NE	NE	NE	NE	NE	NE	NE
Triamcinolone Acetonide	76-25-5	NE	NE	NE	NE	NE	NE	NE	NE
Polyethylene	9002-88-4	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Mineral Oil Exposure limits are for oil mist, mineral	8042-47-5	NE	NE	5	NE	5	10	NE	NE

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

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

TRIAMCINOLONE ACETONIDE:
Russia: STEL = 0.001 mg/m^3, JUN 2003

MINERAL OIL:
Australia: TWA = 5 mg/m^3, JUL 2008
Belgium: = TWA 5 mg/m^3, STEL = 10 mg/m^3, MAR 2002
Denmark: TWA = 1 mg/m^3, MAY 2011
Hungary: CL = 5 mg/m^3, Carcinogen, SEP 2000
Japan: OEL = 3 mg/m^3 (mist), 1 carc, MAY 2012
Korea: TWA = 5 mg/m^3, STEL = 10 mg/m^3, 2006
Mexico: TWA = 5 mg/m^3; STEL = 10 mg/m^3, 2004

MINERAL OIL (continued):
The Netherlands: MAC-TGG = 5 mg/m^3, 2003
New Zealand: TWA = 5 mg/m^3, STEL 10 ppm, JAN 2002
The Philippines: TWA = 5 mg/m^3, JAN 1993
Poland: MAC(TWA) = 5 mg/m^3, MAC(STEL) = 10 mg/m^3, JAN 1999
Russia: STEL = 5 mg/m^3, JUN 2003
Sweden: TWA = 1 mg/m^3; STEL = 3 mg/m^3, JUN 2005
In Argentina, Bulgaria, Colombia, Jordan, Korea, New Zealand, Singapore, Vietnam, New Zealand, Singapore, Vietnam check ACGIH TLV

POLYETHYLENE:
Russia: STEL = 10 mg/m^3, JUN 2003

PROTECTIVE EQUIPMENT: *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, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132)*, equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

Respiratory Protection: Not typically needed under normal circumstances of handling and use. Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT (continued):

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

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

9. PHYSICAL and CHEMICAL PROPERTIES

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

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance may be a property to identify the product in event of accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: ***Combustion:*** If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon and nitrogen oxides, sulfur compounds and hydrogen fluoride).
Hydrolysis: None known.

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

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.

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

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to veterinary employees handling this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

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

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Aminoglycosides have a low order of toxicity in contact with skin; however, rashes and allergic anaphylactoid reactions have occurred in susceptible persons. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Reaction may be life-threatening in certain individuals. Eye contact can cause temporary blurred vision and irritation. Symptoms of eye contact may include redness, pain, and watering.

Skin Absorption: This product can be absorbed into the skin. Symptoms of chronic exposure by this route may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine. Neomycin Sulfate can be absorbed through open wounds, burns, and granulating surfaces. Absorption can be significant and can adversely affect the kidneys and destroy fibers of the acoustic nerve and cause permanent bilateral deafness. When absorbed, Neomycin Sulfate is a nephrotoxic antibiotics (can cause damage to the liver), and the nephrotoxic potentials are additive. Persons handling this product routinely in an animal medical facility should be gloved.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE (continued):

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

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

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

SENSITIZATION OF PRODUCT: Aminoglycosides have a low order of toxicity in contact with skin; however, rashes and allergic anaphylactoid reactions have occurred in some patients. Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest. Rare instances of anaphylactoid reactions have occurred in persons susceptible to corticosteroids. Nystatin has caused bronchospasm, facial swelling, rash, hives (rarely), and Stevens-Johnson (very rarely) have been reported.

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

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

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

TARGET ORGANS:

Acute: Skin.

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

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

NEOMYCIN SULFATE:

Standard Draize Test (Skin-Human) 6 mg/3 days-intermittent: Mild

Standard Draize Test (Skin-Human) 0.2%: Severe

TDLo (Oral-Human) 12,600 mg/kg/7 days: Behavioral: somnolence (general depressed activity), hallucinations, distorted perceptions, anorexia (human)

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

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

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

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

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

LD_{50} (Intramuscular-Mouse) 142 mg/kg

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

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

TDLo (Subcutaneous-Rat) 280 mg/kg/7 days-intermittent: Kidney/Ureter/Bladder: changes in bladder weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases

TDLo (Subcutaneous-Mouse) 560 mg/kg/7 days-intermittent: Gastrointestinal: other changes; Kidney/Ureter/Bladder: other changes in urine composition; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Intravenous-Rat) 15 mg/kg: Behavioral: alteration of classical conditioning

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

TDLo (Intracerebral-Rat) 714.3 µg/kg: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Neurotransmitters or modulators (putative): catecholamine levels in CNS

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

TDLo (Intramuscular-Cat) 5050 mg/kg/14 weeks-intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis), interstitial nephritis; Related to Chronic Data: death

TDLo (Intramuscular-Guinea Pig) 2 gm/kg/8 days-intermittent: Sense Organs and Special Senses (Ear): change in acuity, changes in cochlear structure or function; Related to Chronic Data: death

NYSTATIN:

Standard Draize test (Skin-Woman) 30%

TDLo (Oral-Woman) 40000 units/kg: Skin and Appendages: dermatitis, other (after systemic exposure); Immunological Including Allergic: hypersensitivity delayed

LD_{50} (Oral-Rat) 10 gm/kg

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

LD_{50} (Intravenous-Mouse) 3 mg/kg

LD_{50} (Intraperitoneal-Rat) 24305 µg/kg

LD_{50} (Intraperitoneal-Mouse) 4400 µg/kg

LD_{50} (Subcutaneous-Mouse) 120 mg/kg

TDLo (Oral-Rat) 100 mg/kg: female 9 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death

TDLo (Oral-Rat) 11 gm/kg: female 1-22 day(s) after conception: Reproductive: Fertility: abortion

NYSTATIN (continued):

TDLo (Intravenous-Rat) 42 mg/kg/4 weeks-intermittent: Behavioral: food intake (animal); Skin and Appendages: hair; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intravenous-Rat) 82.5 mg/kg/55 days-intermittent: Behavioral: food intake (animal); Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Intravenous-Rat) 61.5 mg/kg/41 days-intermittent: Nutritional and Gross Metabolic: weight loss or decreased weight gain

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) 18500 µg/kg: female 6-22 day(s) after conception lactating female 20 day(s) post-birth: Reproductive: Maternal Effects: other effects; Effects on Newborn: growth statistics (e.g.%, reduced weight gain), physical

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.%, reduced weight gain)

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

TDLo (Intravenous-Rat) 55.5 mg/kg: female 6-22 day(s) after conception lactating female 20 day(s) post-birth: Reproductive: Specific Developmental Abnormalities: urogenital system

TDLo (Intravenous-Rat) 30 mg/kg: female 6-15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)

TDLo (Intravenous-Rabbit) 39 mg/kg/13 days-intermittent: Behavioral: food intake (animal); Liver: changes in liver weight

TDLo (Intravenous-Rabbit) 39 mg/kg: female 6-18 day(s) after conception: Reproductive: Maternal Effects: other effects

TDLo (Intravenous-Mammal-Dog) 180 mg/kg/90 days-intermittent: Kidney/Ureter/Bladder: changes in tubules (including acute renal failure, acute tubular necrosis); Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol)

TDLo (Subcutaneous-Rat) 0.053 gm/kg: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TCLo (Inhalation-Rat) 5 mg/m3/4 hours /17 weeks-intermittent: Immunological Including Allergic: hypersensitivity delayed

TCLo (Inhalation-Rat) 40 mg/m3/24 hours /10 days-continuous: Immunological Including Allergic: decrease in humoral immune response; Biochemical: Metabolism (Intermediary): Plasma proteins not involving coagulation

TCLo (Inhalation-Guinea pig) 5 mg/m3/4 hours /17 weeks-intermittent: Immunological Including Allergic: hypersensitivity delayed

Cytogenetic Analysis (Parenteral-Mouse) 50 mg/kg

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

TRIAMCINOLONE ACETONIDE:

Standard Draize Test (Skin-Human) 0.1%/2 days
Standard Draize Test (Skin-Woman) 1%: Moderate
Standard Draize Test (Skin-Woman) 0.01%: Mild
TDLo (Skin-Human) 1.7 µg/kg/8 days-intermittent: Skin and Appendages: dermatitis, other (after systemic exposure)
TDLo (Skin-Woman) 101 mg/kg: female 12-29 week(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: gastrointestinal system
TDLo (Intramuscular-Man) 571 µg/kg: Vascular: shock; Skin and Appendages: dermatitis, other (after systemic exposure); Immunological Including Allergic: anaphylaxis
TDLo (Parenteral-Woman) 4 mg/kg: Behavioral: muscle weakness; Vascular: BP elevation not characterized in autonomic section
TDLo (Parenteral-Woman) 2 mg/kg: Behavioral: muscle weakness; Vascular: BP elevation not characterized in autonomic section; Blood: hemorrhage
TDLo (Ocular-Human) 0.057 mg/kg: Sense Organs and Special Senses (Eye): increased intraocular pressure
TDLo (Ocular-Human) 0.057 mg/kg: Sense Organs and Special Senses (Eye): increased intraocular pressure, effect, not otherwise specified
TCLo (Inhalation-Human) 18.8 mg/kg/3 years-intermittent: Musculoskeletal: osteoporosis
TCLo (Inhalation-Human) 4680 µg/kg/39 weeks-intermittent: Lungs, Thorax, or Respiration: other changes
LD_{50} (Oral-Rat) 1451 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: respiratory stimulation; Blood: hemorrhage
LD_{50} (Oral-Mouse) 5 gm/kg
LD_{50} (Oral-Mouse) 2168 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: respiratory stimulation; Blood: hemorrhage
LD_{50} (Subcutaneous-Rat) 13100 µg/kg
LD_{50} (Subcutaneous-Mouse) 132 mg/kg
LD_{50} (Intraperitoneal-Mouse) 105 mg/kg
TCLo (Inhalation-Rat) 0.2 mg/m3/4 hours: Behavioral: changes in motor activity (specific assay); Liver: other changes, changes in liver weight
TCLo (Inhalation-Rat) 0.2 mg/m3/4 hours: Kidney/Ureter/Bladder: changes in kidney weight; Endocrine: hyperglycemia, changes in thymus weight
TCLo (Inhalation-Rat) 0.2 mg/m3/4 hours: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol), changes in other cell count (unspecified); Nutritional and Gross Metabolic: body temperature decrease
TCLo (Inhalation-Rat) 0.9 mg/m3/4 hours: Endocrine: other changes; Blood: leukopenia
TDLo (Intraperitoneal-Mouse) 1 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: hepatic microsomal mixed oxidase (dealkylation, hydroxylation, etc
TDLo (Intraperitoneal-Mouse) 13 mg/kg: female 12 day(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo
TDLo (Subcutaneous-Rat) 450 µg/kg: female 11-19 day(s) after conception: Reproductive: Maternal Effects: parturition; Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Effects on Newborn: growth statistics (e.g.%, reduced weight gain)
TDLo (Subcutaneous-Rat) 900 mg/kg: female 11-19 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death
TDLo (Subcutaneous-Rat) 1 mg/kg: female 14-15 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Rat) 2 mg/kg: female 14-15 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants
TDLo (Subcutaneous-Mouse) 12800 µg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)
TDLo (Subcutaneous-Mouse) 960 µg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 2500 µg/kg: female 12 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death; Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 12800 µg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)

TRIAMCINOLONE ACETONIDE (continued):

TDLo (Ocular-Rabbit) 0.95 mg/kg: Sense Organs and Special Senses (Eye): corneal damage
TDLo (Intramuscular-Rat) 375 µg/kg: female 12-14 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Intramuscular-Rat) 500 µg/kg: female 14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), Effects on Embryo or Fetus: other effects to embryo
TDLo (Intramuscular-Rat) 750 µg/kg: female 12-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: body wall
TDLo (Intramuscular-Rat) 1500 µg/kg: female 12-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system
TDLo (Intramuscular-Rat) 750 µg/kg: female 12-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants), litter size (e.g. # fetuses per litter; measured before birth); Effects on Embryo or Fetus: fetal death
TDLo (Intramuscular-Mouse) 480 µg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo
TDLo (Intramuscular-Mouse) 5 mg/kg: female 11 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue
TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: cytological changes (including somatic cell genetic material)
TDLo (Intramuscular-Mouse) 10 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death; Specific Developmental Abnormalities: craniofacial (including nose and tongue
TDLo (Intramuscular-Hamster) 500 µg/kg: female 9 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: Central Nervous System, other developmental abnormalities
TDLo (Intramuscular-Hamster) 100 µg/kg: female 11 day(s) after conception: Reproductive: Specific Developmental Abnormalities: endocrine system; Effects on Newborn: biochemical and metabolic
TDLo (Intramuscular-Primate-Monkey) 50 mg/kg: female 23-31 day(s) after conception: Reproductive: Specific Developmental Abnormalities: Central Nervous System, eye/ear, craniofacial (including nose and tongue)
TDLo (Intramuscular-Primate-Monkey) 60 mg/kg: female 41-44 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), musculoskeletal system, blood and lymphatic systems (including spleen and marrow)
TDLo (Intramuscular-Primate-Monkey) 60 mg/kg: female 41-44 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death
TDLo (Intramuscular-Primate-Monkey) 50 mg/kg: female 23-31 day(s) after conception: Reproductive: Specific Developmental Abnormalities: homeostasis
TDLo (Intramuscular-Primate-Monkey) 3 mg/kg: female 63-65 day(s) after conception: Reproductive: Specific Developmental Abnormalities: respiratory system
TDLo (Inhalation- Primate-Monkey) 7.252 µg/kg/14 days-intermittent: Endocrine: changes in thymus weight; Lungs, Thorax, or Respiration: other changes
TDLo (Inhalation- Primate-Monkey) 28742 µg/kg/14 days-intermittent: Endocrine: changes in adrenal weight; Lungs, Thorax, or Respiration: changes in lung weight; Related to Chronic Data: changes in testicular weight
TDLo (Implant-Mouse) 650 µg/kg: female 6-18 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Implant-Mouse) 6500 µg/kg: female 6-18 day(s) after conception: Reproductive: Fertility: pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)
Mutation Test Systems-Not Otherwise Specified (Skin-Human) 5000 ppm
Mutation Test Systems-Not Otherwise Specified (Skin-Human) 5000 ppm
Unscheduled DNA Synthesis (Human Cells-Not Otherwise Specified) 1 nmol/L
DNA Inhibition (Human Cells-Not Otherwise Specified) 10 nmol/L
DNA Inhibition (Mouse Cells-Not Otherwise Specified) 1 nmol/L
DNA Inhibition (Mouse Leukocyte) 10 nmol/L

THIOSTREPTON:

LD_{50} (Oral-Mouse) > 1 gm/kg
LD_{50} (Intraperitoneal-Mouse) 2 gm/kg
LD_{50} (Intravenous-Mouse) 41 mg/kg
LD_{50} (Intramuscular-Mouse) 1 gm/kg

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

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

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC INFORMATION (continued):

Nystatin: No long-term animal studies have been performed to evaluate carcinogenic potential of Nystatin.

Triamcinolone Acetonide: Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids.

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

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

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: The following information is available for some active ingredients.

Mutagenicity: No studies available.

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

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

Embryotoxicity/Teratogenicity:

Neomycin Sulfate: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and there have been several reports of total irreversible, bilateral congenital deafness in children whose mothers received streptomycin (a related aminoglycoside) during pregnancy. Although serious side effects to the fetus or newborns have not been reported in the treatment of pregnant women with other aminoglycosides, the potential for harm exists.

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

Triamcinolone Acetonide:

Human Data: As a group, corticosteroids have not been associated with congenital malformations in humans.

Animal Data: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Reproductive Toxicity: No human adverse effects on fertility have been described for this product. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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

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

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

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

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIOACCUMULATION: This product has not been tested for bioconcentration.

ECOTOXICITY: No specific in formation is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated terrestrial and aquatic plant and animal life, especially in large quantities. The following aquatic toxicity data are available for some active ingredients.

NYSTATIN:

EC_{50} (Green algae) 72 hours = 1 µg/ mL (= 0.001 mg/L)

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

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

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

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

13. DISPOSAL CONSIDERATIONS (Continued)

DISPOSAL METHODS (continued): This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

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

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

PREPARING WASTES FOR DISPOSAL: This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this product should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

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

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION 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.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

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

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

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

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The Neomycin Sulfate component is listed on the California Proposition 65 lists; however, this listing applies when Neomycin Sulfate is used internally and does not apply to this product. Aminoglycosides are listed on the California Proposition 65 lists. WARNING! This product contains a compound known to the State of California to cause developmental harm.

Other U.S. Federal Regulations: Not applicable.

CANADIAN REGULATIONS:

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

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Canadian WHMIS Classification and Symbols: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING!** INGESTION MAY BE HARMFUL. PROLONGED SKIN CONTACT MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE RESPIRATORY SYSTEM AND EYE IRRITATION. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY, BASED ON ANIMAL DATA. MAY BE COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not taste or swallow. Avoid skin or contact with clothing. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, call a physician immediately. Do NOT induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

CLASSIFICATION FOR COMPONENTS:

Full Text CLP 1272/2008/Global Harmonization:

Neomycin Sulfate: This is a self-classification.

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

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

Nystatin: The following is a Self-Classification.

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

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

Thiostrepton: The following is a Self-Classification.

Classification: Acute Oral Toxicity Category 4

Hazard Statements: H302: Harmful if swallowed.

Triamcinolone Acetonide: The following is a Self-Classification.

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

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

Mineral Oil: The following is a Self-Classification.

Classification: Aspiration Hazard Category 1

Hazard Statements: H304: May be fatal if swallowed and enters airways.

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

REVISION DETAILS: October 2015: Up-date of entire SDS to include European and Global Harmonization classification.
REFERENCES AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

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DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

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

EXPOSURE LIMITS IN AIR (continued):

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A–C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

IDLH: Immediately Dangerous to Life and Health. This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantitation.

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

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

NIC: Notice of Intended Change.

DEFINITION OF TERMS (Continued)

EXPOSURE LIMITS IN AIR (continued):

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

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL" is placed next to the PEL that was vacated by Court Order.

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

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

TLV: Threshold Limit Value. An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

TWA: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: **0** Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation*: Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation*: Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. *Oral Toxicity LD_{50} Rat*: > 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: > 20 mg/L. **1** Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. *Skin Irritation*: Slightly or mildly irritating. PII or Draize > 0 < 5. *Eye Irritation*: Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. *Oral Toxicity LD_{50} Rat*: > 500–5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000–2000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 2–20 mg/L.**2** *Moderate Hazard*: Temporary or transitory injury may occur; prolonged exposure may affect the CNS. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. *Eye Irritation*: Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. *Oral Toxicity LD_{50} Rat*: > 50–500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200–1000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.5–2 mg/L. **3** Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation*: Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5–8, with destruction of tissue. *Eye Irritation*: Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD_{50} Rat*: > 1–50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20–200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05–0.5 mg/L. **4** Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure; extremely toxic; irreversible injury may result from brief contact. *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 LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L.

FLAMMABILITY HAZARD: **0** Minimal Hazard: Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes. **1** Slight Hazard: Materials that must be pre-heated before ignition can occur. Material requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class IIIB); and Most ordinary combustible materials (e.g. wood, paper, etc.). **2** Moderate Hazard: Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres with air. This usually includes the following: Liquids having a flash-point at or above 37.8°C (100°F); Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); and Solids and semisolids (e.g. viscous and slow flowing as asphalt) that readily give off flammable vapors. **3** Serious Hazard: Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions. This usually includes the following: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38°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. OSHA Class IB and IC); Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air (e.g., dusts of combustible solids, mists or droplets of flammable liquids); and Materials that burn extremely rapidly, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). **4** Severe Hazard: Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. OSHA Class IA); and Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric).

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD: **0** *Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react.). **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the 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. 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, 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 confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must 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 psig]. *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 chlorate 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 have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers.

DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **2 (continued):** Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC_{50} for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD_{50} for 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 eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD_{50} for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC_{50} 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 ten times its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} 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, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according 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 IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water 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 must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures 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 Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of 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, sisal, and hemp. Solids and semisolids 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. **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 IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). 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 that are readily dispersed in air 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 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite 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.

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 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

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. LEL: 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. LD_{50}: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC_{50}: 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/m^3: 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. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, 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.

REPRODUCTIVE TOXICITY INFORMATION:

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.

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_{OW} 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:

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

REVISION HISTORY

Date	**Changes**
October 22, 2015	Up-date to include European and Global Harmonization Standard compliance and classification.