MATERIAL SAFETY DATA SHEET
Prepared to U.S. OSHA, CMA, ANSI, and Canadian WHMIS

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

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Clotrimazole and Betamethasone Dipropionate Cream

DESCRIPTION: Clotrimazole and Betamethasone Dipropionate Cream
NDC #: 0168-0258-15, 0168-0258-46
CHEMICAL NAME (for active ingredients): 1-(o-Chloro-α,α-diphenylbenzyl)imidazole/9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-Dipropionate
CHEMICAL FAMILY (for active ingredients): Chlorinated Imidazole/Corticosteroid
HOW SUPPLIED: Cream
PRODUCT USE: Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER’S NAME: FOUGERA PHARMACEUTICALS INC.
ADDRESS: 60 Baylis Road
Melville, NY 11747
BUSINESS PHONE/GENERAL MSDS INFORMATION: 1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico): 1-800-424-9300 (24-hr)
EMERGENCY PHONE (OUTSIDE U.S.): + 1-631-454-7677

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 white to off-white cream with a slight 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, Clotrimazole, Betamethasone Dipropionate, other imidazoles, or any of the other components may experience allergic reactions to this product. Repeated skin exposure to Betamethasone Dipropionate may cause adverse reproductive effects, based on animal data. Flammability Hazards: If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, hydrogen fluoride, and hydrogen chloride). 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>
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<tbody>
<tr>
<td>Betamethasone Dipropionate</td>
<td>5593-20-4</td>
<td>0.06%</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>1.00%</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Ceteareth-30</td>
<td>68439-49-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8012-95-1</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Cetostearyl Alcohol</td>
<td>67762-27-0</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Water and other components. Each</td>
<td></td>
<td></td>
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<tr>
<td>of the other components is present</td>
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<td></td>
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<tr>
<td>than 1 percent concentration</td>
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<td></td>
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<tr>
<td>(0.1% concentration for potential</td>
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<td></td>
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<tr>
<td>carcinogens, reproductive toxins,</td>
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<tr>
<td>respiratory tract sensitizers,</td>
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<tr>
<td>and mutagens):</td>
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<td></td>
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<tr>
<td>The remaining components do not</td>
<td></td>
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<tr>
<td>contribute any significant</td>
<td></td>
<td></td>
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<td>additional hazards.</td>
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<td></td>
</tr>
<tr>
<td>Balance</td>
<td></td>
<td></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.

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

EYE EXPOSURE: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then “roll” eyes while flushing. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.
### 4 FIRST-AID MEASURES (Continued)

**INHALATION:** If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

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

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

**RECOMMENDATIONS TO PHYSICIANS:** This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

### 5. FIRE-FIGHTING MEASURES

**FLASH POINT:** Not applicable.

**AUTOIGNITION TEMPERATURE:** Not applicable.

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

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

**UNSUITABLE FIRE EXTINGUISHING MEDIA:** None known.

**SPECIAL FIRE AND EXPLOSION HAZARDS:** If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, hydrogen fluoride, and hydrogen chloride).

**Explosion Sensitivity to Mechanical Impact:** Not sensitive.

**Explosion Sensitivity to Static Discharge:** Not sensitive.

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

### 6. ACCIDENTAL RELEASE MEASURES

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

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

**Large Spills:** Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: *triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.* Absorb spilled liquid using polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

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

### 7. HANDLING and USE

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

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

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>ACGIH-TLVs TWA mg/m³</th>
<th>OSHA-PELs STEL mg/m³</th>
<th>NIOSH-RELs TWA mg/m³</th>
<th>NIOSH IDLH mg/m³</th>
<th>AIHA WEELs TWA = 10 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Betamethasone Dipropionate</td>
<td>5593-20-4</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Ceteareth</td>
<td>68439-49-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Cetostearyl Alcohol</td>
<td>67762-27-0</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>8012-95-1</td>
<td>5 (inhalable fraction)</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

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

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

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


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

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

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not established.  
FREEZING/MELTING POINT: Not established.  
EVAPORATION RATE (nBuAc = 1): Not established.  
SOLUBILITY IN WATER: Partially soluble.  
VAPOR PRESSURE (air = 1): Not established.  
SPECIFIC GRAVITY @ 50°C (water = 1): 0.84–1.02  
ODOR THRESHOLD: Not established.  
pH: 4.5–6.5  
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.  
APPEARANCE AND COLOR: This product is a white to off-white cream with a slight 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

REACTIVITY/CHEMICAL STABILITY: This product is stable.  
DECOMPOSITION PRODUCTS: Decomposition: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, hydrogen fluoride, and hydrogen chloride). Hydrolysis: None known.
10. STABILITY and REACTIVITY (Continued)

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 redness and itching. Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. Corticosteroids (such as Betamethasone Dipropionate) may cause allergic contact dermatitis. This is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Eye contact can cause irritation, stinging, redness, and tearing.

SKIN ABSORPTION: The Betamethasone Dipropionate 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 or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.

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, Clotrimazole, Betamethasone Dipropionate, other imidazoles, or any of the other components may experience allergic reactions to this product. Persons using the product in therapeutic doses may experience redness and itching. Persons using the product in therapeutic doses may experience burning, stinging, itching, irritation, redness, blistering, peeling, swelling, hives, dryness, inflammation of hair follicles, excessive hair growth, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, striae, and prickly heat.

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

SENSITIZATION OF PRODUCT: Corticosteroids (such as Betamethasone Dipropionate) may cause allergic contact dermatitis. The Benzyl Alcohol component of this product is a weak skin sensitizer; skin contact may cause an allergic reaction in sensitive individuals. Rarely, the Cetostearyl Alcohol component of this product can cause allergic skin reaction with hives.

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. Eye contact will cause irritation.

Chronic: Corticosteroids (such as Betamethasone Dipropionate) 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.
REPRODUCTIVE TOXICITY INFORMATION:
Currently, there are no ACGIH Biological Exposure Indices (BEIs). There have been no long-term studies performed in animals to evaluate the reproductive toxicity of this compound.

CARCINOGENIC INFORMATION:
There have been no long-term studies performed in animals to evaluate the carcinogenic potential of Clotrimazole or topical corticosteroids. 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: Betamethasone was positive in the in vitro human lymphocyte chromosome aberration assay, and equivocal in the in vivo mouse bone marrow micronucleus assay. It was negative in the bacterial mutagenicity assay (Salmonella typhimurium and Escherichia coli), and in the mammalian cell mutagenicity assay (CHO/HGPRT).

Embryotoxicity: This product has not been tested for embryotoxic effects.

Teratogenicity: Betamethasone Dipropionate has been shown to be teratogenic in rabbits when given by the intramuscular route at doses of 0.05 mg/kg. This dose is approximately 0.2 fold the maximum human dose based on a mg/m² comparison. The abnormalities observed included umbilical hernias, cephaloceles, and cleft palates. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. No human data are available.

Reproductive Toxicity: Reproductive studies with Betamethasone Dipropionate carried out in rabbits at doses of 1.0 mg/kg by the intramuscular route and in mice up to 33 mg/kg by the intramuscular route indicated no impairment of fertility except for dose-related increases in fetal resorption rates in both species. These doses are approximately 5 and 38 fold the human dose based on a mg/m² comparison, respectively. No human data are available.

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

CLOTRIMAZOLE (continued):

BETAMETHASONE DIPROPIONATE (continued):

CLOTRIMAZOLE:

BETAMETHASONE DIPROPIONATE:
LD₅₀ (Oral-rat) > 4 g/kg
LD₅₀ (Oral-mouse) > 5 g/kg: Behavioral: antipsychotic
Skin and Appendages: hair
Skin: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; Nutritional and Gross Metabolism: weight loss or decreased weight gain

LD₅₀ (Subcutaneous-rat) 15600 µg/kg/26 weeks/intermittent: Endocrine: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; changes in leucocyte (WBC) count

LD₅₀ (Subcutaneous-rat) 10 g/kg/26 weeks/intermittent: Endocrine: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; changes in leucocyte (WBC) count

Betamethasone was positive in the IARC-3 (Not Classifiable as to Carcinogenicity to Humans)

TOXICITY DATA:

Toxicology DATA: The toxicity data available for the active components of this product are presented in this MSDS. Additional data are available for the incipient components of this product, but are not presented in this MSDS; Contact Fougera, Inc. for more information.

BETAMETHASONE DIPROPIONATE:
LD₅₀ (Oral-rat) > 4 g/kg
LD₅₀ (Oral-mouse) > 5 g/kg: Behavioral: antipsychotic
Skin and Appendages: hair
Skin: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; Nutritional and Gross Metabolism: weight loss or decreased weight gain

LD₅₀ (Subcutaneous-rat) 15600 µg/kg/26 weeks/intermittent: Endocrine: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; changes in leucocyte (WBC) count

LD₅₀ (Subcutaneous-rat) 10 g/kg/26 weeks/intermittent: Endocrine: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; changes in leucocyte (WBC) count

Betamethasone was positive in the IARC-3 (Not Classifiable as to Carcinogenicity to Humans)

TOXICITY DATA:

Toxicology DATA: The toxicity data available for the active components of this product are presented in this MSDS. Additional data are available for the incipient components of this product, but are not presented in this MSDS; Contact Fougera, Inc. for more information.

BETAMETHASONE DIPROPIONATE:
LD₅₀ (Oral-rat) > 4 g/kg
LD₅₀ (Oral-mouse) > 5 g/kg: Behavioral: antipsychotic
Skin and Appendages: hair
Skin: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; Nutritional and Gross Metabolism: weight loss or decreased weight gain

LD₅₀ (Subcutaneous-rat) 15600 µg/kg/26 weeks/intermittent: Endocrine: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; changes in leucocyte (WBC) count

LD₅₀ (Subcutaneous-rat) 10 g/kg/26 weeks/intermittent: Endocrine: changes in skin thickness; Blood: changes in erythrocyte (RBC) count; changes in leucocyte (WBC) count

Betamethasone was positive in the IARC-3 (Not Classifiable as to Carcinogenicity to Humans)

11. TOXICOLOGICAL INFORMATION (Continued)
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. The following information is available for the components of this product:

BENZYL ALCOHOL:
- Experimental Koc values for Benzyl Alcohol are < 5 for three different soils; Apison (0.11% organic carbon), Fullerton (0.06% organic carbon), and Dormont (1.2% organic carbon). An experimental Koc value of 15 is determined for Benzyl Alcohol on a red-brown Australian soil (1.09% organic carbon). According to a classification scheme, these Koc values suggest that Benzyl Alcohol is expected to have very high mobility in soil.

PROPYLENE GLYCOL:
- The Koc of Propylene Glycol is estimated as 8, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that Propylene Glycol is expected to have very high mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. The following information is available for the components of this product:

BENZYL ALCOHOL:
- If released to air, a vapor pressure of 0.094 mm Hg at 25°C indicates Benzyl Alcohol will exist solely as a vapor in the ambient atmosphere. Vapor-phase Benzyl Alcohol 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 17 hours. If released to soil, Benzyl Alcohol is expected to have very high mobility based on Koc values of less than 5 to 15 measured in various soils. Volatilization from moist soil surfaces is not expected to be an important fate process based on an estimated Henry's Law constant of 3.1X10-7 atm-cu m/mole. Benzyl Alcohol is not expected to volatilize rapidly from dry soil surfaces based on its vapor pressure. Benzyl Alcohol is expected to undergo biodegradation under both aerobic and anaerobic conditions based upon results in a number of aerobic biodegradation tests. If released into water, Benzyl Alcohol is not expected to adsorb to suspended solids and sediment based upon the Koc data. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 75 days and 2.2 years, respectively. Hydrolysis is not expected to be an important environmental fate process since Benzyl Alcohol lacks hydrolyzable functional groups.

PROPYLENE GLYCOL:
- Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that Propylene Glycol is expected to have very high mobility in soil. Volatilization of Propylene Glycol from moist soil surfaces is not expected to be an important fate process given an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/liter. Propylene Glycol is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Laboratory experiments using agricultural soils from South Carolina conducted at 22 deg C and a f fortification of 1,000 ppm Propylene Glycol, yielded 73-78% mineralization during a 51 day incubation period, suggesting that biodegradation will be an important fate process in soils. Based on a classification scheme, an estimated Koc value of 8, determined from a log Kow of -0.92 and a regression-derived equation, indicates that Propylene Glycol is not expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is not expected based upon an estimated Henry's Law constant of 1.3X10-8 atm-cu m/mole, derived from its vapor pressure, 0.13 mmHg, and water solubility, 1X10+6 mg/L. Numerous screening studies using wastewater or sewage inoculum as seed, suggests that Propylene Glycol will be degraded readily under aqueous environments. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Propylene Glycol, which has a vapor pressure of 0.13 mmHg at 25°C, is not expected to be a vapor in the ambient atmosphere. Vapor-phase Propylene Glycol is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 32 hours, calculated from its constant of 1.2X10-11 cu m/mol-sec at 25°C.

BIOACCUMULATION: This product has not been tested for bioconcentration. The following information is available for the components of this product:

BENZYL ALCOHOL:
- An estimated BCF of 1 was calculated for Benzyl Alcohol, using a log Kow of 1.1 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

PROPYLENE GLYCOL:
- An estimated BCF of 3 was calculated for Propylene Glycol, using a log Kow of -0.92 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Toxicity Endpoint</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>E. coli</td>
<td>NOEC</td>
<td>3 hours = 30 mg/L</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Daphnia magna</td>
<td>EC50</td>
<td>30 minutes = 71 mg/L</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Chlorella pyrenoidosa</td>
<td>EC100</td>
<td>92,000 mg/L</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Pseudomonas putida</td>
<td>EC50</td>
<td>16 hours = 658 mg/L</td>
</tr>
</tbody>
</table>

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.
13. DISPOSAL CONSIDERATIONS (Continued)

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

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

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

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

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

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

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

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

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

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not on the California Proposition 65 lists.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CANADIAN REGULATIONS:

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

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

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

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE ALLERGIC REACTION. MAY CAUSE SKIN AND EYE IRRITATION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, 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.

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 Fougera’s knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846
DATE OF PRINTING: February 1, 2012
DEFINITION OF TERMS

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

**CHEMICAL HAZARD RATINGS**

**HAZARD MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS**

**PHYSICAL HAZARD**

**SLOW HEAT-DEFERRED HAZARD**

**PYROLYTIC MATERIALS**

**THERMAL HAZARD**

**UNHEATED HAZARD**

**UNLABELED MATERIAL**

**UNLABELED UNTESTED SAMPLE**

**WATER ACTIVITY**

**WATER ACTIVITY RATING**

**WATER ACTIVITY RATING SYSTEM**

**WATER ACTIVITY UNIT**

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HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): 3 (continued): 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 time of a 1:1 perchloric acid (50%)/cellulose mixture. Definitions:

Reactive: 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 in this mixture with air. May 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 pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

DEFINITION OF TERMS (Continued):

FLAMMABILITY LIMITS IN AIR:

MUCH OF THE REPRODUCTIVE-RELATED INFORMATION IS BASED UPON STUDIES WITH ANIMALS. OTHER INFORMATION INCLUDES DATA FROM HUMAN STUDIES, LABORATORY DATA, AND DATA FROM SITUATIONS SIMILAR TO THOSE ENCOUNTERED AT THE WORK SITE.

LITHIUM IS A CHEMICAL THAT CAUSES DAMAGE TO A DEVELOPING FETUS, 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 TOXICANT IS ANY SUBSTANCE THAT INTERFERES IN ANY WAY WITH THE REPRODUCTIVE PROCESS.

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 toxic 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.

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine how much the concentration will change as a result of uptake by plant or animal matter. TLM: Median threshold limit. log Kow or log Koc: Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.
DEFINITION OF TERMS (Continued)

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.

REGULATORY INFORMATION (continued):
CANADA:
### REVISION HISTORY

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>January 31, 2012</td>
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