MATERIAL SAFETY DATA SHEET

HYDROCORTISONE CREAM 0.5%, 1.0%, AND 2.5% MSDS

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

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Hydrocortisone Cream 0.5%, 1.0%, and 2.5%

DESCRIPTION: Hydrocortisone Cream

NDC #: 0168-0014-31; 0168-0154-08; 0168-0154-31; 0168-0015-16; 0168-0015-31; 0168-0080-16; 0168-0080-31

CHEMICAL NAME (for active ingredient): Hydrocortisone [pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β,)]

CHEMICAL FAMILY (for active ingredient): Corticosteroid

HOW SUPPLIED: 0.5%, 1.0%, and 2.5% Cream

FORMULA (for active ingredient): C₂₁H₃₀O₅

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-hrs)

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 cream with a slightly fatty 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 ingredient, Hydrocortisone, or any other components of this product may experience allergic reactions to this product. Repeated skin exposure to Corticosteroids (such as Hydrocortisone) 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). Reactivity Hazards: This product is not reactive. Environmental Hazards: This product has not been tested for environmental effects. Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone</td>
<td>50-23-7</td>
<td>0.5%, 1.0%, and 2.5%</td>
</tr>
<tr>
<td>Isopropyl Palmitate</td>
<td>142-91-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Sorbitan Monostearate</td>
<td>1338-41-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Paraffin</td>
<td>64742-43-4</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Polyoxy 40 Stearate</td>
<td>9004-99-3</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Glycerol Monostearate</td>
<td>123-94-4</td>
<td>Proprietary</td>
</tr>
</tbody>
</table>

Water and other components. Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens). The remaining components do not contribute any significant additional hazards.

Balance

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

4 FIRST-AID MEASURES

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

SKIN EXPOSURE: If adverse skin effects occur, discontinue use. Seek medical attention.
4 FIRST-AID MEASURES (Continued)

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. 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 established.
AUTOIGNITION TEMPERATURE: Not established.
FLAMMABLE LIMITS (in air by volume, %): Not established.
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). 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 and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge. Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus. Absorb spilled liquid using polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Monitor area and confirm levels are bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area. 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.
7. HANDLING and USE (Continued)

WORK PRACTICES AND HYGIENE PRACTICES (continued): Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

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

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

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

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

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

EXPOSURE LIMITS/GUIDELINES:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>ACGIH-TLVs STEL</th>
<th>OSHA-PELs TWA</th>
<th>NIOSH-PELs TWA</th>
<th>NIOSH OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone</td>
<td>50-23-7</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Benzylic Alcohol</td>
<td>100-51-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>10 (mist)</td>
<td>15 (total dust)</td>
<td>5 (resp. fraction)</td>
<td>10 (total) 5 (resp. fraction)</td>
</tr>
<tr>
<td>Glyceryl Monostearate (Exposure limits are for Steareate)</td>
<td>123-94-4</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Isopropyl Palmitate</td>
<td>142-91-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Paraffin</td>
<td>64742-43-4</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Polyoxy 40 Stearate (Exposure limits are for Steareate)</td>
<td>9004-99-3</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Sorbitan Monostearate (Exposure limits are for Steareate)</td>
<td>1338-41-6</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established NIC = Notice of Intended Change See Section 16 for Definitions of Terms Used.

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

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


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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point</td>
<td>135°C (275°F)</td>
</tr>
<tr>
<td>Evaporation Rate (nBuAc = 1)</td>
<td>0.07</td>
</tr>
<tr>
<td>Vapor Pressure (air = 1)</td>
<td>Not established</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not established</td>
</tr>
<tr>
<td>Coefficient Water/Oil Distribution</td>
<td>Not established</td>
</tr>
<tr>
<td>Appearance and Color</td>
<td>This product is a white cream with a slightly fatty odor.</td>
</tr>
</tbody>
</table>

10. STABILITY and REACTIVITY

**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 oxides).
- **Hydrolysis:** None known.

**Materials with Which Substance is Incompatible:** This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

**Hazardous Polymerization:** Will not occur.

**Conditions to Avoid:** Avoid heat, light, and contact with incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

**Symptoms of Overexposure by Route of Exposure:** The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

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

- **Contact with Skin or Eyes:** Skin contact may cause burning sensation, stinging, pricking, itching, and tingling. Corticosteroids (such as Hydrocortisone) 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 Hydrocortisone 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 Hydrocortisone component of this product or any other components of this product may experience allergic reactions to this product. Persons using the product in therapeutic doses may experience burning, itching, irritation, dryness, inflammation of hair follicles, excessive growth of hair, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, skin atrophy, striae, and pricky heat.

**Irritancy of Product:** This product may mildly to moderately irritate contaminated tissue.

**Sensitization of Product:** Corticosteroids (such as Hydrocortisone) 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.
REPRODUCTIVE TOXICITY INFORMATION:

MOBILITY: All work practices must be aimed at eliminating environmental contamination.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs):

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

HYDROCORTISONE: Standard Draize Test (Skin-Rabbit) 1000 ppm: Mild

LD₅₀ (Oral-Rat) 5120 mg/kg: Eye; ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD₅₀ (Oral-Mouse) 6720 mg/kg: Sense Organs and Special Senses (Eye); ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD₅₀ (Intrapitoneal-Rat) 1420 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD₅₀ (Intrapitoneal-Mouse) 1660 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD₅₀ (Subcutaneous-Rat) 3260 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD₅₀ (Subcutaneous-Mouse) 1980 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

TD₅₀ (Skin-Rabbit) 82,500 µg/kg: female 7-17 days after conception: Effects on Newborn: growth statistics (e.g., reduced weight gain)

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

HYDROCORTISONE (continued):

- GLYCERYL MONOSTEARATE (as a stearate compound):
  - ACGIH TLV-A4 (Not Classifiable as Human Carcinogen);
  - POLYOXYL 40 STEARATE (as a stearate compound):
  - ACGIH TLV-A4 (Not Classifiable as Human Carcinogen);
  - SORBITAN MONOSTEARATE (as a stearate compound):

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 active component of this product, Hydrocortisone, is rated as Pregnancy Category C (RISK CANNOT BE RULED OUT; Human evidence is lacking, but animal evidence is positive). Listed below is information concerning the effects of this compound on animal or human reproductive systems.

- Mutagenicity/Embryotoxicity:
- Teratogenicity:
- Reproductive Toxicity:

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

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 of 15 was 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.
MOBILITY (continued):

GLYCERIN:
Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1.220.000 mg/L at 5°C, soil adsorption coefficients for Glycerin can be estimated at 3 and 2, respectively, using regression-derived equations. The magnitude of these values indicate that glycine will display very high mobility in soil.

ISOPROPYL PALMITATE:
Using a structure estimation method based on molecular connectivity indices, the Koc for Isopropyl Palmitate can be estimated to be about 52,000. According to a classification scheme, this estimated Koc value suggests that Isopropyl Palmitate is expected to be immobile in soil.

SORBITOL:
The Koc of Sorbitol is estimated as approximately 2, using a log Kow of -2.2 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that Sorbitol is not expected to have very high mobility in soil.

STEARYL ALCOHOL:
Soil Adsorption/Mobility: The Koc of Octadecanol is estimated as 1.8X10^5, using a water solubility of 1.1X10^-3 mg/L at 25°C and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that 1-octadecanol is expected to be immobile 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 upon 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 upon an estimated Henry's Law constant of 3.1X10^-7 atm-cu/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 aqueous biodegradation tests. Isopropyl alcohol is not expected to adsorb to suspended solids and sediment based upon the Koc value. 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.

GLYCERIN:
If released to soil, glycine is expected to undergo rapid biodegradation under aerobic conditions. It is expected to display very high mobility in soil and it is not expected to significantly volatilize to the atmosphere. If released to water, glycine is expected to rapidly degrade under aerobic conditions. Biodegradation in sewage and under anaerobic conditions is also expected. Glycine is not expected to bioconcentrate in fish and aquatic organisms nor is it expected to adsorb to sediment and suspended organic matter. Volatilization to the atmosphere is expected to be slower then for water itself. If released to the atmosphere, Glycerin may undergo a gas-phase oxidation with photochemically produced hydroxyl radicals with a half-life of 33 hrs. It may also undergo atmospheric removal by wet deposition processes.

ISOPROPYL PALMITATE:
If released to air, an estimated vapor pressure of 5.6X10^-5 mm Hg at 25°C indicates Isopropyl Palmitate will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase Isopropyl Palmitate 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. Particulate-phase Isopropyl Palmitate will be removed from the atmosphere by wet and dry deposition. If released to soil, Isopropyl Palmitate is expected to have no mobility based upon an estimated Koc of 52,000. Volatilization from moist soil surfaces is expected to be an important fate process based upon an estimated Henry's Law constant of 0.016 atm-cu/mole. However, adsorption to soil is expected to attenuate volatilization. Isopropyl Palmitate is expected to rapidly biodegrade in aerobic soils as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. If released into water, Isopropyl Palmitate is expected to adsorb to suspended solids and sediment in the water column based upon the estimated Koc. Isopropyl Palmitate is expected to rapidly biodegrade in aerobic waters as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. Volatilization from water surfaces is 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 5 hours and 7 days, respectively. However, volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant.

SORBITOL:
If released to air, an estimated vapor pressure of 4.9X10^-9 mm Hg at 25°C indicates Sorbitol will exist in the particulate phase. Particulate-phase Sorbitol will be removed from the atmosphere by wet and dry deposition. If released to soil, Sorbitol is expected to have very high mobility based upon an estimated Koc of 2. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 7.3X10^-13 atm-cu/mole. Sorbitol is a simple sugar alcohol and should be readily biodegraded in the environment. If released into water, Sorbitol is not expected to adsorb to suspended solids and sediment in the water column based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant.

STEARYL ALCOHOL:
Based on a classification scheme, an estimated Koc value of 1.8X10^5, determined from a water solubility of 1.1X10^-3 mg/L and a regression-derived equation, indicates that Octadecanol is expected to be immobile in soil. Volatilization of Octadecanol from moist soil surfaces may be expected to be an important fate process given an estimated Henry's Law constant of 8.4X10^-4 atm-cu/mole, derived from a vapor pressure of 2.7X10^-6 mmHg, its water solubility. However, adsorption to soil is expected to attenuate volatilization. Octadecanol is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Biodegradation of Octadecanol may be an important fate process in soil based on a mixed shake flask culture study. Based on a classification scheme, an estimated Koc value of 1.8X10^5, determined from a water solubility of 1.1X10^-3 mg/L and an expression-derived equation, indicates that Octadecanol is expected to adsorb to suspended solids and sediments in the water column, based upon the estimated Koc. Octadecanol is expected to rapidly biodegrade in aerobic soils as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. Volatilization from water surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant and an estimation method, volatilization half-lives for a model river and model lake are 2.8 hours and 7 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column. A percent theoretical oxygen demand value of 0.3 in 24 hrs using a Warburg test suggests that biodegradation may not be an important fate process in water. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Octadecanol, which has a vapor pressure of 2.7X10^-6 mm Hg at 25°C, will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase Octadecanol is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be about 14 hours. The calculated log Kow constant of 2.67X10^-11 atm-cu/mole-sec at 25°C that is derived using a structure estimation method. Particulate-phase 1-Octadecanol may be removed from the air by wet or dry deposition. Using the Warburg test which employs activated sludge, Octadecanol gave a theoretical oxygen demand of 0.3, 0.5, and 0.3 percent in 6, 12, and 24 hours. However, using an acclimated mixed shake flask culture with incremental substrate addition of 1-octadecanol, biomass yield reached 54.5 percent after seven days. Given sufficient time in contact with adapted microbial species under conditions otherwise non-limiting, the complete disappearance of 1-octadecanol as identifiable molecular species will occur.

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.

GLYCERIN:
Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1.220.000 mg/L at 5°C, bioconcentration factors for Glycerin can be estimated at 3 and 0.2, respectively, using regression-derived equations. The magnitude of these values indicate that bioconcentration of Glycerin in fish and aquatic organisms will not be significant. Log Koc = -1.76.

ISOPROPYL PALMITATE:
An estimated BCF of 53 was calculated for Isopropyl Palmitate using an estimated log Kow of 8.16 and a regression-derived equation. According to a classification scheme, this estimated BCF suggests the potential for bioconcentration in aquatic organisms is moderate.

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

STEARYL ALCOHOL:
An estimated BCF value of 2.8X10^4 was calculated for Octadecanol, using an experimental water solubility of 1.1X10^-3 mg/L at 25°C and a recommended regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is very high, provided the compound is not metabolized by the organism.
12. ECOLOGICAL INFORMATION (Continued)

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.

**BENZYL ALCOHOL:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LC50 (Goldfish) 24 hours</th>
<th>EC50 (Green algae) 7 days</th>
<th>EC10 (Hydrilla) 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia</td>
<td>&gt; 5,000 mg/L</td>
<td>&gt; 10,000 mg/L</td>
<td>&gt; 10,000 mg/L</td>
</tr>
<tr>
<td>Lake Superior water</td>
<td>&gt; 23°C</td>
<td>&gt; 18-22°C</td>
<td>&gt; 18-22°C</td>
</tr>
</tbody>
</table>

**GLYCERIN:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOEC (Trichophyton mentagrophytes) 5 days</th>
<th>NOEC (Candida albicans) 24 hours</th>
<th>NOEC (E. coli) 48 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichophyton mentagrophytes</td>
<td>10 g/L</td>
<td>10 g/L</td>
<td>30 mg/L</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>10 g/L</td>
<td>&gt; 3.3 mg/L</td>
<td>&gt; 10,000 mg/L</td>
</tr>
<tr>
<td>E. coli</td>
<td>10 mg/L</td>
<td>&gt; 10,000 mg/L</td>
<td>&gt; 10,000 mg/L</td>
</tr>
</tbody>
</table>

**STEARYL ALCOHOL:**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC0 (Anabaena variabilis) 7 days</th>
<th>EC50 (Photobacterium phosphoreum) 5 minutes</th>
<th>EC0 (Scenedesmus quadricauda) 4 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabaena variabilis</td>
<td>&gt; 10,000 mg/L</td>
<td>&gt; 5 mg/L</td>
<td>&gt; 5 mg/L</td>
</tr>
<tr>
<td>Photobacterium phosphoreum</td>
<td>&gt; 5 mg/L</td>
<td>&gt; 5 mg/L</td>
<td>&gt; 5 mg/L</td>
</tr>
<tr>
<td>Scenedesmus quadricauda</td>
<td>&gt; 5 mg/L</td>
<td>&gt; 5 mg/L</td>
<td>&gt; 5 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.

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

**EXPOSURE LIMITS IN AIR:**

- **CEILING LEVEL:** The concentration that shall not be exceeded during any part of the workday.

- **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.

- **NICE:** Notice of Intended Change.

- **NIOSH:** National Institute for Occupational Safety and Health.

- **NIOSH RELs:** NIOSH's Recommended Exposure Limits.

- **PEL:** OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TEL, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limit was developed by the American Conference of Governmental Industrial Hygienists (ACGIH) for use in the workplace. A Permissible Exposure Limit (PEL) refers to the level of concentration of a substance in the air to which workers can be exposed during an 8-hour workday (or 40-hour workweek). The limit is set to prevent adverse health effects, including cancer, and to protect the worker from developing any type of acute or chronic illness.

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

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

**DEFINITION OF TERMS**

- **EXPOSURE LIMITS IN AIR (continued):**
  - **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 a limit above which it is generally considered that all workers may be exposed without adverse effect. The duration must be considered, including the 8-hour TWA.
  - **TWA:** Time Weighted Average exposure concentration for a conventional 8-hr (TLV) or up to a 10-hr (REL) workday and a 40-hr workweek.

- **WEEL:** Workplace Environmental Exposure Limit from the ACGIH.

- **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:** Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. Skin Irritation: Essentially non-irritating. Mechanical irritation may occur. Dermal Toxicity: LD50 Rat or Rabbit: > 1000 mg/kg. Eye Irritation: Essentially non-irritating. Minimal effects clearing in 24 hours. LD50 Rat or Rabbit: > 20 mg/kg. Irritation: Slightly irritating and/or corrosive; may cause a temporary or transitory injury; no destruction of dermal tissue. Eye Irritation: Slightly irritating and/or corrosive; may cause a temporary or transitory injury; no destruction of dermal tissue.

- **Flammability Hazard:** Minimal Hazard: Materials that must not burn in air when exposed to a temperature of 975°F (150°C) 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 975°F (150°C) 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 III); and Most ordinary combustible materials (e.g., wood, paper, etc.).
DEFINITION OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): Compressed Gases: No Rating. Oxidizers: Any liquid or gaseous material that, either in concentration tested, exhibits a mean burning time less than or equal to 5 seconds. Ducts and mists with an LD50 for acute oral toxicity greater than 5 mg/kg but less than or equal to 200 mg/kg. Materials with an LD50 for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg.

NFPA 704: Flammable liquids: Ignitible under almost all ambient temperature and/or pressure conditions. Gases: Ignitible under almost all ambient temperature and/or pressure conditions. Solids: Ignitible under almost all ambient temperature and/or pressure conditions. Oxidizers: Any liquid or gaseous material that, either in concentration tested, exhibits a mean burning time less than or equal to 5 seconds. Ducts and mists with an LD50 for acute oral toxicity greater than 5 mg/kg but less than or equal to 200 mg/kg. Materials with an LD50 for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg.

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 LC50 for acute oral toxicity greater than 5 mg/kg but less than or equal to 500 mg/kg. Materials with an LC50 for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 5000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes, and skin. 1 Materials that, under emergency conditions, can cause temporary incapacitation or respiratory injury. Gases with an LC50 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 LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 5,000 ppm but greater than 3,000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC50 for acute inhalation toxicity greater than 10 mg/L but less than or equal to 50 mg/L and for which the vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 3,000 ppm but greater than 1000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 1000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 300 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 30 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 3 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 0.3 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC50 for acute inhalation toxicity, if its LC50 is less than or equal to 0.03 ppm.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HYDROCORTISONE CREAM 0.5%, 1.0%, AND 2.5% MSDS PAGE 9 OF 11 EFFECTIVE DATE: JANUARY 31, 2012
DEFINITION OF TERMS (Continued):

FLAMMABILITY HAZARD (continued): 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 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. 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.

INSTABILITY HAZARD: 0 Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1 Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. 2 Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100 W/mL. 3 Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that in themselves are 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 elevated temperatures and pressures. 4 Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to thermal or mechanical shock at elevated 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 needed to determine the limits 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. LDLo: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC50: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/m3: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TD50: LD50, and LD95: 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 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. A reproductive toxic 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 Kow or log Koc: Coefficient of Oil/Water Distribution is used to assess a substance’s behavior in the environment.

REGULATORY INFORMATION:
U.S.: EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure regulations. This section also includes information on the precautionary warnings that appear on the material’s package label.

CANADA:
<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 31, 2012</td>
<td>Remove comma from company name.</td>
</tr>
<tr>
<td>December 23, 2011</td>
<td>Company name change correction.  Change of heading text, Section 5.  Review and up-date of exposure limits to current, Section 8.  Change text on Reproductive Toxicity, Section 11.  Revision to Definition of Terms.  Up-date Section 12.  Revise Canadian WHMIS status. Move ANSI Labeling to Section 16.  Add revision history section.</td>
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