SAFETY DATA SHEETS

This SDS packet was issued with item:

078485116

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

078938066 078946077

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: **Betamethasone Valerate Cream 0.1%**

DESCRIPTION:	Betamethasone Valerate Cream
NDC #:	0168-0040-15, 0168-0040-46
CHEMICAL NAME (for active ingredient):	9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-Valerate
CHEMICAL FAMILY (for active ingredient):	Corticosteroid
HOW SUPPLIED:	0.1% Cream
FORMULA (for active ingredient):	$C_{27}H_{37}FO_6$
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, odorless, opaque cream. ***Health Hazards:*** Employees administering the product should not experience adverse effects if handled properly. 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, Betamethasone Valerate (or any other components of this product) may experience allergic reactions to this product. Repeated skin exposure to Betamethasone Valerate 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 and hydrogen fluoride). ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situations to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/w
Betamethasone Valerate	2152-44-5	0.1%
Chlorocresol	59-50-7	Proprietary
PEG 1000 Monocetyl Ether	9004-95-9	Proprietary
Mineral Oil	8012-95-1	Proprietary
Cetostearyl Alcohol	67762-27-0	Proprietary
White Petrolatum	8009-03-8	Proprietary
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.

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.

4 FIRST-AID MEASURES (Continued)

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.

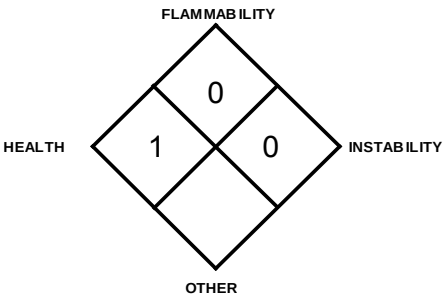
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

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 and hydrogen fluoride).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



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

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. 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:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Betamethasone Valerate	2152-44-5	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	67762-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Chlorocresol	59-50-7	NE	NE	NE	NE	NE	NE	NE	DFG MAK: Danger of sensitization of the skin
Mineral Oil	8012-95-1	5 (inhalable fraction)	NE	NE	NE	NE	NE	NE	NE
PEG 1000 Monocetyl Ether	9004-95-9	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE

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).

EYE PROTECTION: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-07.

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

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

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: 100°C (212°F)
FREEZING/MELTING POINT: 40–50°C (100–122°F)
EVAPORATION RATE (nBuAc = 1): 0.02
SOLUBILITY IN WATER: Partially Soluble.
VAPOR PRESSURE (air = 1): Not established.
SPECIFIC GRAVITY (water = 1): < 1.0
ODOR THRESHOLD: Not established.
pH: 4–6
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
APPEARANCE AND COLOR: This product is a white, odorless, opaque cream.
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: Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and hydrogen fluoride). Hydrolysis: None known.

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

10. STABILITY and REACTIVITY (Continued)

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 of this product 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, prickling, itching, and tingling. Corticosteroids (such as Betamethasone Valerate) 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 Valerate component of this product can be absorbed through intact skin. Symptoms of chronic overexposure by this route may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

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.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

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

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 "Other Potential Health Effects".

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing the Betamethasone Valerate 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 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 Valerate) may cause allergic contact dermatitis. The Chlorocresol component of this product can cause allergic contact dermatitis. 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. Although unlikely, inhalation can irritate the respiratory system. Eye contact will cause irritation.

Chronic: Corticosteroids (such as Betamethasone Valerate) may cause allergic contact dermatitis. Symptoms of chronic skin absorption exposure may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

TARGET ORGANS:

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

Chronic: Occupational Exposure: Skin. *Therapeutic Doses:* Skin, endocrine system.

TOXICITY DATA: Only 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.

BETAMETHASONE VALERATE:
LD_{50} (Oral-rat) > 3 g/kg; Skin and Appendages: hair
LD_{50} (Oral-mouse) 4067 mg/kg

BETAMETHASONE VALERATE (continued):
LD_{50} (Intraperitoneal-rat) > 4500 mg/kg; Skin and Appendages: hair

BETAMETHASONE VALERATE (continued):
LD_{50} (Intraperitoneal-mouse) 632 mg/kg
LDLo (Subcutaneous-rat) 2 g/kg

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

BETAMETHASONE VALERATE (continued):

LD_{50} (Subcutaneous-mouse) 496 mg/kg

LD_{50} (Subcutaneous-rabbit) 61200 µg/kg; Eye: lacrymation; Gastrointestinal: hypermotility, diarrhea

TDLo (skin-rat) 87500 mg/kg/35 days-intermittent: Endocrine: changes in thymus weight; Blood: changes in leukocyte (WBC) count; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (ski-rat) 9 mg/kg/30 days-intermittent: Blood; changes in bone marrow (not otherwise specified); Nutritional and Gross Metabolic: weight loss or decreased weight gain; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (skin-rat) 18 mg/kg/26 weeks-intermittent: Cardiac: changes in heart weight; Liver: changes in liver weight; Blood: changes in leukocyte (WBC) count

TDLo (skin-rat) 42 mg/kg/5 weeks-intermittent: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol), changes in leukocyte (WBC) count; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (skin-rat) 19,800 µg/kg/female 7–17 days after conception; Reproductive: Maternal Effects: parturition; Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death

TDLo (skin-rat) 19800 µg/kg/female 7–17 days after conception; Reproductive: Effects on Newborn: stillbirth, live birth index (measured after birth), sex ratio

BETAMETHASONE VALERATE (continued):

TDLo (skin-rat) 19800 µg/kg/female 7–17 days after conception; Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TDLo (skin-dog) 91 mg/kg/91 days/intermediate; Kidney, Ureter, Bladder: urine volume increased; Endocrine: changes in adrenal & thymus weight

TDLo (skin-rabbit) 7500 µg/kg/female 7–18 days after conception; Reproductive: Fertility: abortion; Effects on Fetus: fetal death; Effects on Newborn: stillbirth

TDLo (skin-rabbit) 1500 µg/kg/female 7–18 days after conception; Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)

TDLo (Subcutaneous-rat) 3500 µg/kg/35 days/intermediate; Liver: changes in liver weight; Endocrine: changes in adrenal weight; Blood: changes in leukocyte (WBC) count

TDLo (Subcutaneous-rat) 44 mg/kg/female 7–17 days after conception; Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Effects on Fetus: fetal death

TDLo (Subcutaneous-rat) 175 mg/kg/35 days/intermediate; Nutritional and Gross Metabolic: weight loss or decreased weight gain; Related to Chronic Data: death

TDLo (Subcutaneous-rat) 12 mg/kg/30 days/intermediate; Endocrine: changes in spleen weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Related to Chronic Data: changes in uterine weight

BETAMETHASONE VALERATE (continued):

TDLo (Subcutaneous-rat) 1100 µg/kg/female 7–17 days after conception; Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus); Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TDLo (Subcutaneous-rat) 44 mg/kg/female 7–17 days after conception; Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), body wall

TDLo (Subcutaneous-mouse) 1 mg/kg/female 11 days after conception; Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)

TDLo (Subcutaneous - mouse) 1 mg/kg/female 14 days after conception; Reproductive: Effects on Fetus: fetal death

TDLo (Subcutaneous-mouse) 3300 µg/kg/female 12 days after conception; Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Subcutaneous-rabbit) 1300 µg/kg/female 6–18 days after conception; Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)

TDLo (Subcutaneous-rabbit) 1300 µg/kg/female 6–18 days after conception; Reproductive: Effects on Fetus: fetal death; Specific Developmental Abnormalities: Central Nervous System, eye/ear

TDLo (Subcutaneous-rabbit) 1300 µg/kg/female 6–18 days after conception; Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), body wall, musculoskeletal system

CARCINOGENIC INFORMATION: Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. 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, Betamethasone Dipropionate, 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 product and its components 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: Animal studies have not been performed to evaluate the embryotoxicity of Betamethasone Dipropionate. No human data are available.

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/m^2 comparison. The abnormalities observed included umbilical hernias, cephalocele, 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 does are approximately 5 and 38 fold the human dose based on a mg/m^2 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.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

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

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

BIOACCUMULATION: This product has not been tested for bioconcentration.

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

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

13. DISPOSAL CONSIDERATIONS

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

13. DISPOSAL CONSIDERATIONS (Continued)

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

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

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

PREPARING WASTES FOR DISPOSAL: 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): Chlorocresol = 5000 lb (2268 kg)

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

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): 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): **WARNING!** MAY CAUSE ALLERGIC SKIN REACTION. MAY CAUSE SKIN AND EYE IRRITATION. Avoid prolonged or repeated contact with skin and clothing. Avoid contact with eyes. Wash thoroughly after handling. Wear gloves, safety glasses, 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, 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, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

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:

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

EXPOSURE LIMITS IN AIR:

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

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

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

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

LOQ: Limit of Quantitation.

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

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

NIC: Notice of Intended Change.

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

NIOSH RELs: NIOSH's Recommended Exposure Limits.

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

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

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

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

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

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

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

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

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **4** Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposures; extremely toxic; irreversible injury may result from brief contact. *Skin Irritation*: Not appropriate. Do not rate as a 4, based on skin irritation alone. *Eye Irritation*: Not appropriate. Do not rate as a 4, based on eye irritation alone. *Oral Toxicity LD_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L.

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

PHYSICAL HAZARD: **0** *Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react.). **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors. **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture.

DEFINITION OF TERMS (Continued)

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 pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC_{50} for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD_{50} for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC_{50} for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg.

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): **2 (continued):** Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

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

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. LD_{50}: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC_{50}: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/m^3: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects.

Cancer Information: IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

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

DEFINITION OF TERMS (Continued)

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. log K_{OW} or log K_{OC}: Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S.:

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

CANADA:

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

REVISION HISTORY

Date	**Changes**
January 31, 2012	Remove comma from company name.
December 5, 2011	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.

SAFETY DATA SHEET

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

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

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

TRADE NAME/MATERIAL NAME: Betamethasone Valerate Cream 0.1%

DESCRIPTION:	Betamethasone Valerate Cream 0.1%
NDC #:	0168-0040-15, 0168-0040-46
CHEMICAL NAME (for active ingredient):	9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-Valerate
CHEMICAL FAMILY:	Synthetic Adrenocorticosteroid
HOW SUPPLIED:	0.1% Topical Betamethasone Valerate Cream
FORMULA (for active ingredient):	$C_{27}H_{37}FO_6$
RELEVANT USE of the SUBSTANCE:	Pharmaceutical for Human Use
USES ADVISED AGAINST	Other than Relevant Use
SUPPLIER/MANUFACTURER'S NAME:	**FOUGERA PHARMACEUTICALS INC.**
ADDRESS:	60 Baylis Road Melville, NY 11747
BUSINESS PHONE/GENERAL SDS INFORMATION:	1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico):	CHEMTEL: (U.S, Canada, Int'l) 1(813) 676-1670 (24 hrs)

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

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

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: Product Description: This product is a white, odorless, opaque cream. ***Health Hazards:*** The chief health hazard associated with exposure during normal use and handling is the potential for mild irritation of contaminated skin. Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment. Manifestations of Cushing's syndrome, high blood sugar, and excretion of glucose into the urine have been reported. Rarely, immediate hypersensitivity reactions or contact dermatitis may occur from therapeutic use in sensitive individuals. One excipient ingredient has been shown to cause skin sensitization in individuals susceptible to chlorocresols. Use can lead to slow wound-healing and a weakened immune system. Long-term use may result in bone density loss. There is limited evidence of harm to the fetus during pregnancy, 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, sodium, nitrogen and sulfur oxides, phosgene, hydrogen chloride, and hydrogen fluoride). ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** Although this product has not been tested for environmental effects, the Chlorocresol component can cause acute toxicity in aquatic organisms. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENT				
Betamethasone Valerate 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-Valerate	2152-44-5	218-439-5	0.1%	SELF-CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 3, Harmful, Irritant Risk Phrase Codes: R63, R38, R33 Hazard Symbols: Xn/xi GHS and EU 1272/2008 Classification: Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 5, Skin Irritation Cat. 2, STOT (Skin, Endocrine System, Bones) RE Cat. 2 Hazard Codes: H361d, H303, H315, H373 Hazard Symbol/Pictogram: GHS07, GHS08

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

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
EXCIPIENTS				
Cetostearyl Alcohol	67762-27-0	267-008-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Chlorocresol	59-50-7	200-431-6	Proprietary	EU 67/548 Classification: Harmful, Irritant, Dangerous for the Environment Risk Phrase Codes: R21/22, R41, R43, R50 Hazard Symbols: Xn/X, N GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Acute Dermal Toxicity Cat. 4, Eye Damage Cat. 1B, Skin Sensitization Cat. 1, Aquatic Acute Toxicity Cat. 1 Hazard Codes: H302 + H312, H318, H317, H400 Hazard Symbol/Pictogram: GHS05 GHS07, GHS08, GHS09
Mineral Oil	8042-47-5	232-455-8	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Carcinogenic Cat. 3 Risk Phrases: R40 Hazard Symbol: Xn EU/GHS 1272/2008 Classification: Carcinogenic Cat. 2, Eye Irritation Cat. 2B Hazard Statement Codes: H351, H320 Hazard Symbol/Pictogram: GHS08
Polyethylene Glycol 100 Monocetyl Ether	9004-95-9	Not Listed	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Not Applicable GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: None Applicable
White Petrolatum	8009-03-8	232-373-2	Proprietary	EU 67/548 Classification: Carcinogenic Cat. 2 Risk Phrase Codes: R45 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Carcinogenic Cat. 1B Hazard Codes: H350 Hazard Symbol/Pictogram: GHS08
Water and other trace components of less than 1% concentration			Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.

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

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

4 FIRST-AID MEASURES

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

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

Skin Exposure: If adverse skin effects occur, 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.

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

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

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

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions, including skin conditions, hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, and glucosuria may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to this material, or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

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

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available.

AUTOIGNITION TEMPERATURE: Not available.

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

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

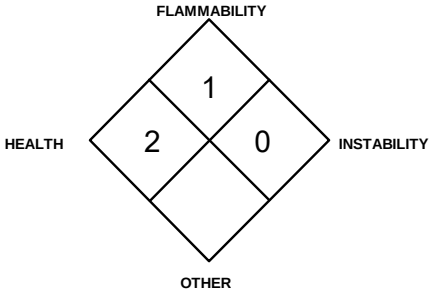
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product contains a skin sensitizer and so presents a contact hazard to firefighters. If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sodium, nitrogen and sulfur oxides, phosgene, hydrogen chloride, and hydrogen fluoride).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



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

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

6. ACCIDENTAL RELEASE MEASURES

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

PROTECTIVE EQUIPMENT:

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

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

METHODS FOR CLEAN-UP AND CONTAINMENT:

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

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

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

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

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

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

7. HANDLING and USE

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

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

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity).

7. HANDLING and USE (Continued)

CONDITIONS FOR SAFE STORAGE (continued): Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

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

Workplace Exposure Limits/Control Parameters:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Betamethasone Valerate	2152-44-5	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	67762-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Chlorocresol	59-50-7	NE	NE	NE	NE	NE	NE	NE	DFG MAK: Danger of sensitization of the skin
Mineral Oil Exposure limits are for oil mist, mineral	8042-47-5	5 (inhal. fract.)	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3, TLV-A4
Polyethylene Glycol 100 Monocetyl Ether	9004-95-9	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE

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

International Occupational Exposure Limits: Exposure limits available for some excipient components are given below.

MINERAL OIL:
Australia: TWA = 5 mg/m^3, JUL 2008
Belgium: = TWA 5 mg/m^3, STEL = 10 mg/m^3, MAR 2002
Denmark: TWA = 1 mg/m^3, MAY 2011
Hungary: CL = 5 mg/m^3, Carcinogen, SEP 2000
Japan: OEL = 3 mg/m^3 (mist), 1 carc, MAY 2012
Korea: TWA = 5 mg/m^3, STEL = 10 mg/m^3, 2006
Mexico: TWA = 5 mg/m^3; STEL = 10 mg/m^3, 2004
The Netherlands: MAC-TGG = 5 mg/m^3, 2003

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

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132), *equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

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

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

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Creamy, viscous liquid.
COLOR: Opaque.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
ODOR: Odorless
ODOR THRESHOLD: Not established.
BOILING POINT: 100°C (212°F)
FREEZING/MELTING POINT: 40-50°C (100-122°F)
EVAPORATION RATE (nBuAc = 1): 0.02
pH: 4-6
VAPOR PRESSURE (air = 1): Not established.
SPECIFIC GRAVITY (water = 1): < 1.0
SOLUBILITY IN WATER: Partially soluble.
OTHER SOLUBILITIES: Not known.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
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

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, sodium, nitrogen and sulfur oxides, phosgene, hydrogen chloride, and hydrogen fluoride). ***Hydrolysis:*** None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.
POSSIBILITY OF HAZARDOUS REACTIONS/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 EXPOSURE 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 high viscosity of the product, inhalation of mists or sprays of this product, especially in a poorly ventilated space, may cause irritation, coughing, and sneezing.

Contact with Skin or Eyes: Skin contact may cause burning sensation, stinging, prickling, itching, and tingling. Corticosteroids (such as Betamethasone Valerate) may cause allergic contact dermatitis. This is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Specific adverse reactions from topical therapeutic use have included burning, itching, irritation, dryness, infection in the hair follicles, abnormal hair growth, acneiform eruptions, hypopigmentation, small round bumps around mouth, allergic contact dermatitis, skin softening, secondary infection, thinning of skin, stretch marks, sweat rash. Due the presence of Chlorocresol, skin contact may cause an allergic reaction in sensitive individuals; subsequent exposure to very small amounts may cause an allergic reaction once sensitized, with symptoms of redness, itching, welts and irritation. Eye contact can cause irritation, stinging, redness, and tearing.

Skin Absorption: The Betamethasone Valerate component of this product can be absorbed through intact skin. Symptoms of chronic overexposure by this route may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

Ingestion: Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause nausea, vomiting, and diarrhea. Ingestion of large amount may cause systemic effects.

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.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

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

GENERAL TOXICITY INFORMATION: Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment. Manifestations of Cushing's syndrome, high blood sugar, and excretion of glucose into the urine have been reported. Rarely, immediate hypersensitivity reactions or contact dermatitis may occur from therapeutic use in sensitive individuals. Use can lead to slow wound-healing and a weakened immune system. Long-term use may result in bone density loss. There is limited evidence of harm to the fetus during pregnancy, based on animal data.
IRRITANCY OF PRODUCT: This product may irritate contaminated tissue if contact is prolonged.

11. TOXICOLOGICAL INFORMATION (Continued)

SENSITIZATION OF PRODUCT: Due to the presence of the Chlorocresol component, this product may cause skin and/or respiratory sensitization and allergic reaction in susceptible individuals. Rare instances of anaphylactoid reactions have occurred in persons receiving corticosteroid therapy.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure 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 irritation of contaminated skin. Eye contact may cause irritation.

Chronic: Corticosteroids (such as Betamethasone Valerate) may cause allergic contact dermatitis. Symptoms of chronic skin absorption exposure may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

TARGET ORGANS:

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

Chronic: *Occupational Exposure:* Skin. *Therapeutic Doses:* Skin, bones, endocrine, metabolic system.

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

BETAMETHASONE VALERATE:

LD_{50} (Oral-rat) > 3 g/kg; Skin and Appendages: hair
LD_{50} (Oral-mouse) 4067 mg/kg
LD_{50} (Intraperitoneal-rat) > 4500 mg/kg; Skin and Appendages: hair
LD_{50} (Intraperitoneal-mouse) 632 mg/kg
LDLo (Subcutaneous-rat) 2 g/kg
LD_{50} (Subcutaneous-mouse) 496 mg/kg
LD_{50} (Subcutaneous-rabbit) 61200 µg/kg; Eye: lacrymation; Gastrointestinal: hypermotility, diarrhea
TDLo (skin-rat) 87500 mg/kg/35 days-intermittent: Endocrine: changes in thymus weight; Blood: changes in leukocyte (WBC) count; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (ski-rat) 9 mg/kg/30 days-intermittent: Blood; changes in bone marrow (not otherwise specified); Nutritional and Gross Metabolic: weight loss or decreased weight gain; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (skin-rat) 18 mg/kg/26 weeks-intermittent: Cardiac: changes in heart weight; Liver: changes in liver weight; Blood: changes in leukocyte (WBC) count
TDLo (skin-rat) 42 mg/kg/5 weeks-intermittent: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol), changes in leukocyte (WBC) count; Nutritional and Gross Metabolic: weight loss or decreased weight gain
TDLo (skin-rat) 19,800 µg/kg/female 7–17 days after conception; Reproductive: Maternal Effects: parturition; Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death
TDLo (skin-rat) 19800 µg/kg/female 7–17 days after conception; Reproductive: Effects on Newborn: stillbirth, live birth index (measured after birth), sex ratio
TDLo (skin-rat) 19800 µg/kg/female 7–17 days after conception; Reproductive: Specific Developmental Abnormalities: musculoskeletal system
TDLo (skin-dog) 91 mg/kg/91 days/intermediate; Kidney, Ureter, Bladder: urine volume increased; Endocrine: changes in adrenal & thymus weight
TDLo (skin-rabbit) 7500 µg/kg/female 7–18 days after conception; Reproductive: Fertility: abortion; Effects on Fetus: fetal death; Effects on Newborn: stillbirth
TDLo (skin-rabbit) 1500 µg/kg/female 7–18 days after conception; Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)

BETAMETHASONE VALERATE (continued):

TDLo (Subcutaneous-rat) 3500 µg/kg/35 days/intermediate; Liver: changes in liver weight; Endocrine: changes in adrenal weight; Blood: changes in leukocyte (WBC) count
TDLo (Subcutaneous-rat) 44 mg/kg/female 7–17 days after conception; Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Effects on Fetus: fetal death
TDLo (Subcutaneous-rat) 175 mg/kg/35 days/intermediate; Nutritional and Gross Metabolic: weight loss or decreased weight gain; Related to Chronic Data: death
TDLo (Subcutaneous-rat) 12 mg/kg/30 days/intermediate; Endocrine: changes in spleen weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Related to Chronic Data: changes in uterine weight
TDLo (Subcutaneous-rat) 1100 µg/kg/female 7–17 days after conception; Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus); Reproductive: Specific Developmental Abnormalities: musculoskeletal system
TDLo (Subcutaneous-rat) 44 mg/kg/female 7–17 days after conception; Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), body wall
TDLo (Subcutaneous-mouse) 1 mg/kg/female 11 days after conception; Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Subcutaneous - mouse) 1 mg/kg/female 14 days after conception; Reproductive: Effects on Fetus: fetal death
TDLo (Subcutaneous-mouse) 3300 µg/kg/female 12 days after conception; Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-rabbit) 1300 µg/kg/female 6–18 days after conception; Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Subcutaneous-rabbit) 1300 µg/kg/female 6–18 days after conception; Reproductive: Effects on Fetus: fetal death; Specific Developmental Abnormalities: Central Nervous System, eye/ear
TDLo (Subcutaneous-rabbit) 1300 µg/kg/female 6–18 days after conception; Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue), body wall, musculoskeletal system

CARCINOGENIC INFORMATION: No studies available for the product. Long-term animal studies have not been performed to evaluate the carcinogenic potential of Betamethasone Valerate.

The excipient components are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

MINERAL OIL: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

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

REPRODUCTIVE TOXICITY INFORMATION: This product is rated as Pregnancy Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). Listed below is information concerning the effects of this compound on animal or human reproductive systems.

Mutagenicity: Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Embryotoxicity/Teratogenicity: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Reproductive Toxicity: No fertility studies available. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

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

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for 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:

CHLOROCRESOL: The Koc of 3-methyl-4-chlorophenol is 490. According to a classification scheme, this Koc value suggests that 3-methyl-4-chlorophenol is expected to have moderate mobility in soil. The pKa of 3-methyl-4-chlorophenol is 9.55, indicating that this compound will exist partially in the anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. The chemical was found to be mobile in an activated carbon-sand filter system; this was considered to be indicative of a low adsorption potential in soil systems. 3-Methyl-4-chlorophenol concentration balance was 0.167 µg/L influent, not detected effluent from Steinhaeule, Neu-Ulmin, a major municipal sewage plant in Germany, sampled on March 11, 1998.

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

CHLOROCRESOL: If released to air, a vapor pressure of 5.0X10-2 mm Hg at 25°C indicates 3-methyl-4-chlorophenol will exist solely as a vapor in the atmosphere. Vapor-phase 3-methyl-4-chlorophenol 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 5 hours. 3-Methyl-4-chlorophenol absorbs light at wavelengths > 290 nm, and therefore may be susceptible to direct photolysis by sunlight. If released to soil, 3-methyl-4-chlorophenol is expected to have moderate mobility based upon a Koc of 490. The pKa of 3-methyl-4-chlorophenol is 9.55, indicating that this compound will exist partially in the anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts. Volatilization from moist soil surfaces is expected to be an important fate process based upon an estimated Henry's Law constant of 2.4X10-6 atm-cu m/mole. 3-Methyl-4-chlorophenol may volatilize from dry soil surfaces based upon its vapor pressure. Half-lives of 4.2 days in acidic sandy loam with a low organic content and 1.4 days in basic sandy silt loam with a higher organic carbon content suggest biodegradation may be an important environmental fate process in soil. If released into water, 3-methyl-4-chlorophenol is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Biodegradation test results are conflicting. 3-Methyl-4-chlorophenol was not degraded in 4 weeks using an activated sludge inoculum in the Japanese MITI test perhaps due to microbial toxicity from the high concentration of the test chemical but reached 20-65% of the Theoretical Oxygen Demand after 28 days in the Closed Bottle Test. 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 18 and 134 days, respectively. 3-Methyl-4-chlorophenol is not expected to undergo hydrolysis in the environment because phenols are generally resistant to hydrolysis.

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

CHLOROCRESOL: BCF values of 5.5 to 11 and 6.7 to 13 were measured using initial 3-methyl-4-chlorophenol concentrations of 2 µg/L and 20 µg/L, respectively. Tests were conducted in a continuous flow system with six weeks exposure using carp having an average lipid content of 4.9%. According to a classification scheme, these BCF ranges suggest that 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 some components of this product.

CHLOROCRESOL:

LD_{50} (*Agelains phoeniceus* red-winged blackbird) oral 113 mg/kg
LD_{50} (*Colinus virginianus* Bobwhite quail) oral 1,540 ppm
LD_{50} (*Colinus virginianus* Bobwhite quail) diet > 3,180 ppm for 8 days
EC_{50} (*Chlorella pyrenoidosa* Green Algae) 2x10+6 cells/mL; 72 hours = 15,000 µg/L (95% confidence interval: 12,000-18,000 µg/L)
EC_{50} (*Scenedesmus subspicatus* Green Algae) exponential growth phase; 48 hours = > 10,000 µg/L
EC_{50} (*Scenedesmus subspicatus* Green Algae) exponential growth phase; 72 hours = > 10,000 µg/L
EC_{50} (*Scenedesmus subspicatus* Green Algae) exponential growth phase; 96 hours = > 10,000 µg/L
EC_{50} (*Xenopus sp.* Clawed frog) embryo 8 hours post fertilization; 112 hours = 11,710-12,136 µg/L for (95% confidence interval: 8310-15,962 µg/L)
EC_{50} (*Daphnia magna* Water flea); 24 hour = 2780-5300 µg/L
EC_{50} (*Daphnia magna* Water flea) age 24 hr; 48 hours = 1500 µg/L (95% confidence interval: 1130-1940 µg/L)

CHLOROCRESOL (continued):

LC_{50} (*Pimephales promelas* fathead minnow) 30 day old; 96 hours = 4.05 mg/L (confidence limit 3.11-5.27 mg/L)
LC_{50} (*Pimephales promelas* fathead minnow) weight 106 mg; 24 hours = 13.3 (12.1-14.5) mg/L
LC_{50} (*Pimephales promelas* fathead minnow) weight 106 mg; 48 hours = 11.4 (10.3-12.8) mg/L
LC_{50} (*Pimephales promelas* fathead minnow) weight 106 mg; 72 hours = 9.21 (7.88-10.8) mg/L
LC_{50} (*Pimephales promelas* fathead minnow) weight 106 mg; 96 hours = 7.56 (6.41-8.92) mg/L
LC_{50} (*Daphnids*) 0.17 mg/L
LC_{50} (*Oncorhynchus mykiss* Rainbow trout) 0.9 ppm
LC_{50} (*Daphnia magna* Water Flea) 48 hours = 2.3 ppm
LC_{50} (*Daphnia magna* Water flea) age < 24 hr; 48 hours = 2000 µg/L (95% confidence interval: 1700-2200 µg/L)

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

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

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

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. 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 product should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

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

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

14. TRANSPORTATION INFORMATION

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

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

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

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

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

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

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

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

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

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

U.S. CERCLA Reportable Quantities (RQ): Chlorocresol: 5000 lb (2270 kg)

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

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component is listed on the California Proposition 65 lists.

Other U.S. Federal Regulations: The Chlorocresol component is a Toxic pollutant designated pursuant to section 307(a)(1) of the Federal Water Pollution Control Act and is subject to effluent limitations. Chlorinated phenols (includes trichlorophenols and chlorinated cresols).

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 Chlorocresol component is listed as a Substance With Greatest Potential For Human Exposure Substance on Environment Canada/Health Canada Pilot Project List (CEPA 1999, Section 73). Meets categorization criteria: *may present, to individuals in Canada, the greatest potential for exposure; or *are persistent or bioaccumulative in accordance with the regulations, and inherently toxic to human beings or to non-human organisms, as determined by laboratory or other studies.

Other Canadian Regulations: Not applicable.

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

EUROPEAN REGULATIONS:

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

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

16. OTHER INFORMATION

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

16. OTHER INFORMATION (Continued)

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

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

Betamethasone Valerate: This is a self-classification.
Classification: Reproductive Toxicity Category 2, Acute Oral Toxicity Category 5, Skin Irritation Category 2, Specific Target Organ Toxicity (Skin-Endocrine System, Bones) Category 2
Hazard Statements: H361d: Suspected of damaging the unborn child. H315: Causes skin irritation.H303: May be harmful if swallowed. H373: May cause damage to organs through prolonged or repeated exposure.

Chlorocresol: The following is a Published Classification.
Classification: Acute Oral Toxicity Category 4, Acute Dermal Toxicity Category 4, Eye Damage Category 1B, Skin Sensitization Category 1, Aquatic Acute Toxicity Category 1
Hazard Statements: H302 + H312: Harmful if swallowed or in contact with skin. H318: Causes serious eye damage. H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life.

Cetomacrogol: The following is a Self-Classification.
Classification: Acute Oral Toxicity Category 5
Hazard Statements: H303: May be harmful if swallowed.

Mineral Oil: This is a self-classification.
Classification: Carcinogenic Category 2, Eye Irritation Category 2B
Hazard Statement Codes: H351: Suspected of causing cancer. H320: Causes eye irritation.

White Petrolatum: The following is a Self-Classification.
Classification: Carcinogenic Category 1B
Hazard Statements: H350: May cause cancer.

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

Full Text EU 67/548/EEC:

Betamethasone Valerate: This is a self-classification.
Classification: Reproductive Toxicity Category 3, Harmful, Irritant
Risk Phrases: R63: Possible risk of harm to the unborn child. R38: Irritating to skin. R33: Danger of cumulative effects.

Chlorocresol: The following is a Published Classification.
Classification: Harmful, Irritant, Dangerous for the Environment
Risk Phrases: R21/22: Harmful in contact with skin and if swallowed. R41: Risk of serious damage to eyes. R43: May cause sensitisation by skin contact. R50: Very toxic to aquatic organisms.

Mineral Oil: This is a self-classification.
Classification: Carcinogenic Category 3
Risk Phrases: R40: Limited evidence of a carcinogenic effect.

White Petrolatum: The following is a Self-Classification.
Classification: Carcinogenic Category 2
Risk Phrases: R45: May cause cancer.

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

This 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.

REVISION DETAILS: June 2014: Up-date of entire SDS to include European CLP and the Global Harmonization Standard.
REFERENCES AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.
PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846
DATE OF PRINTING: September 3, 2015

DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

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

EXPOSURE LIMITS IN AIR (continued):

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

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

LOQ: Limit of Quantitation.

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

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

NIC: Notice of Intended Change.

DEFINITION OF TERMS (Continued)

EXPOSURE LIMITS IN AIR (continued):

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

NIOSH RELs: NIOSH's Recommended Exposure Limits.

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

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

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

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

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

WEEL: Workplace Environmental Exposure Limits from the AIHA.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

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

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

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

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD: **0** *Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No 0 rating. *Unstable Reactives*: Substances that will not polymerize, decompose, condense, or self-react.) **1** *Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives*: Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives*: Substances that may decompose condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors. **2** *Water Reactivity*: Materials that may react violently with water. *Organic Peroxides*: Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives*: Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases*: Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3** *Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4** *Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability 4. *Oxidizers*: No 4 rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

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

DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC_{50} for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD_{50} for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC_{50} for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg.

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in according with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

FLAMMABILITY LIMITS IN AIR:

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

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. LD_{50}: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC_{50}: Lethal Concentration (gases) that kills 50% of the exposed animals. ppm: Concentration expressed in parts of material per million parts of air or water. mg/m^3: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDLo: Lowest dose to cause a symptom. TCLo: Lowest concentration to cause a symptom. TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo: Lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** IARC: International Agency for Research on Cancer. NTP: National Toxicology Program. RTECS: Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** BEI: ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

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

ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCF: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLm: Median threshold limit. log K_{OW} or log K_{OC}: Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

This section explains the impact of various laws and regulations on the material. 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. WHMIS: Canadian Workplace Hazardous Materials Information System. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. DSL/NDSL: Canadian Domestic/Non-Domestic Substances List. 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.

REVISION HISTORY

Date	**Changes**
September 3, 2015	Change emergency number to CHEMTEL.
June 10, 2014	Up-date to include current GHS & to add EU compliance.
October 3, 2012	New