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: Hydrocortisone Cream 0.5%, 1.0% and 2.5%

DESCRIPTION:	Hydrocortisone Cream
NDC #:	0168-0014-31; 0168-0154-08; 0168-0154-31; 0168-0015-16; 0168-0015-31; 0168-0080-16; 0168-0080-31
CHEMICAL NAME (for active ingredient):	Hydrocortisone [pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β,)]
CHEMICAL FAMILY (for active ingredient):	Corticosteroid
HOW SUPPLIED:	0.5, 1.0 and 2.5% Hydrocortisone Cream
FORMULA (for active ingredient):	$C_{21}H_{30}O_5$
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 translucent, white to off-white, smooth creamy liquid with a mild, fatty odor. ***Health Hazards:*** May be harmful if accidentally ingested. Eye contact can cause irritation. Prolonged skin contact may cause irritation and systemic effects as described under therapeutic use. Skin contact may cause sensitization and allergic skin reactions. In therapeutic use, the most common adverse reactions reported have included burning, itching, irritation, dryness, infection in the hair follicles, abnormal hair growth, acne, hypopigmentation, small bumps around mouth, allergic contact dermatitis, tissue softening, secondary infection, skin atrophy, stripping of skin and sweat rash. Inhibition of bone formation, suppression of calcium absorption and delayed wound healing have been reported. Repeated skin exposure to corticosteroids (such as Hydrocortisone) may cause adverse reproductive effects, based on animal data. May cause harm to fetus, as a corticosteroid. Additional adverse effects are described in Section 11 (Toxicological Information). ***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 gases (e.g., carbon and nitrogen oxides, stearates, acrolein). ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	**LABEL ELEMENTS** **EU Classification (67/548/EEC)** **GHS & EU Classification (1272/2008 EC)** **Risk Phrases/Hazard Statements**
ACTIVE INGREDIENT				
Hydrocortisone Pregn-4-ene-3,20-dione,11,17,21-trihydroxy-,(11β)	50-23-7	200-020-1	0.5, 1.0 and 2.5%	SELF CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 3, Harmful, Irritant Risk Phrases: R63, R38, R43 Hazard Symbol: Xn/Xi EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Acute Dermal Toxicity Cat. 5, Acute Inhalation Toxicity Cat. 5, Skin Irritation Cat. 2, Skin Sensitization Cat. 1 Hazard Statement Codes: H361d, H315, H303 + H313 + H333, H317 Hazard Symbol/Pictogram: GHS07, GHS08

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

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**
EXCIPIENTS				
Benzyl Alcohol	100-51-6	200-289-5	Proprietary	EU 67/548 Classification: Harmful Risk Phrases: R20/22 Hazard Symbols: Xn GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Acute Inhalation Cat. 4 Hazard Codes: H302 + H332 Hazard Symbol/Pictogram: GHS07
Glycerin	56-81-5	200-282-5	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Glyceryl Monostearate	123-94-4	204-664-3	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Isopropyl Palmitate	142-91-6	205-571-1	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Irritant Risk Phrases: R38 Hazard Symbols: Xi GHS & EU 1272/2008 Classification: Skin Irritation Cat. 3 Hazard Codes: H316 Hazard Symbol/Pictogram: None Applicable
Paraffin	64642-43-1	265-145-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Polyoxyl 40 Stearate	9004-99-3	Not Listed	Proprietary	SELF CLASSIFICATION Classification: Irritant Risk Phrases: R36/37/38 Hazard Symbols: Xi GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Skin Irritation Cat. 2, Eye Irritation Cat. 2A, STOT (Inhalation-Respiratory Irritation) Cat. 3 Hazard Codes: H303, H315, H319, H335 Hazard Symbol/Pictogram: GHS07
Sorbitan Monostearate	1338-41-6	215-664-9	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Stearyl Alcohol	112-92-5	204-017-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
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 dermatitis and other skin disorders, hypothyroidism, liver cirrhosis, ocular herpes simplex, seizure disorders, renal insufficiency, osteoporosis, adrenocortical insufficiency, psychic conditions, pre-existing infections or systemic fungal infections may be aggravated by exposure to this product.

4 FIRST-AID MEASURES (Continued)

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: 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.

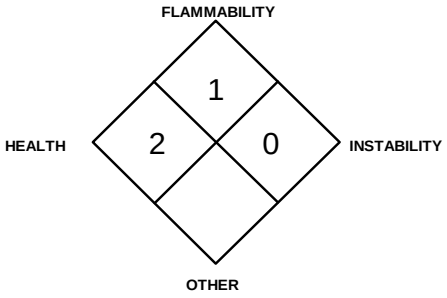
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: 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 gases (e.g., carbon and nitrogen oxides, stearates, acrolein).

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.

7. HANDLING and USE (Continued)

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

SPECIFIC END USE(S): This product is a 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/m³	*STEL mg/m³*	*TWA mg/m³*	*STEL mg/m³*	*TWA mg/m³*	*STEL mg/m³*	*IDLH mg/m³*	*mg/m³*
Hydrocortisone Acetate	50-23-7	NE	NE	NE	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10 ppm
Glycerin	56-81-5	NE	NE	Mist: 15 (total dust), 5 (resp. fract.)	NE	NE	NE	NE	DFG MAKS: TWA = 50 (inhalable fraction) PEAK = 2•MAK 15 min. average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C
Glyceryl Monostearate Polyoxy 40 Stearate Sorbitan Monostearate Exposure limits given are for stearates	1323-39-3 9004-99-3 123-94-4	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Paraffin Exposure limits given are for paraffin wax fume	64742-43-4	2	NE	NE	NE	2	NE	NE	NE
Stearyl Alcohol	112-92-5	NE	NE	NE	NE	NE	NE	NE	NE

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

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

BENZYL ALCOHOL:
Finland: TWA = 10 ppm (45 mg/m³), SEP 2009
Russia: STEL = 5 mg/m³, Skin, JUN 2003

GLYCERIN:
Belgium: TWA = 10 mg/m³, MAR 2002
Finland: TWA = 20 mg/m³, NOV 2011
France: VME = 10 mg/m³, FEB 2006
Germany: MAK = 50 mg/m3, inhal, 2011
Korea: TWA = 10 mg/m³ (mist), 2006
Mexico: TWA = 10 mg/m³ (inhalable), 2004
The Netherlands: MAC-TGG = 10 mg/m³, 2003
New Zealand: TWA = 10 mg/m³ (mist), JAN 2002
Peru: TWA = 10 mg/m³, JUL 2005
Switzerland: MAK-W = 50 mg/m³, KZG-W = 100 mg/m³, inhal, JAN 2011
United Kingdom: TWA = 10 mg/m³, OCT2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

STEARYL ALCOHOL:
Austria: MAK 224 mg/m³ (20 ppm), JAN 2006

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).

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT (continued):

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

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

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

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Smooth, creamy liquid.
COLOR: White to off-white.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
ODOR: Mildly fatty.
ODOR THRESHOLD: Not established.
BOILING POINT: 135°C (275°F)
MELTING POINT: 60°C (140°F)
EVAPORATION RATE (nBuAc = 1): Not available.
SOLUBILITY IN WATER: Soluble.
VAPOR PRESSURE (air = 1): Not established.
SPECIFIC GRAVITY (water = 1): Not available.
ODOR THRESHOLD: Not established.
pH: Not available.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

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

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

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

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

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Will not occur.

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

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. 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. Persons sensitive to corticosteroids or sulfur may experience allergic reactions as described under 'Sensitization of Product'.

Contact with Skin or Eyes: Skin contact may cause mild irritation and acne-form eruptions. Prolonged or repeated skin contact may cause stinging, burning, itching, and irritation. Eye contact may cause irritation, burning, redness, and tearing. This product may cause skin sensitization in susceptible individuals. See 'Sensitization of Product' in this Section for further information.

Skin Absorption: Hydrocortisone 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. Other effects are described under 'Other Potential Health Effects'.

Ingestion: Ingestion is not a significant route of occupational exposure. Animal data indicate Hydrocortisone is harmful by ingestion. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea. Ingestion of large amount may cause gastrointestinal effects such as diarrhea, constipation, stomach cramps, and vomiting. These effects are usually mild and rarely require medical intervention.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

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

11. TOXICOLOGICAL INFORMATION (Continued)

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE (continued):

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.

OTHER HEALTH EFFECTS-Therapeutic Use: In therapeutic use, burning, itching, irritation, dryness, inflammation of hair follicles, excessive growth of hair, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, skin atrophy, striae, and prickly heat may occur. 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.

IRRITANCY OF PRODUCT: Can cause irritation of the eyes. Skin irritation may occur with prolonged contact.

SENSITIZATION OF PRODUCT: Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis. This is usually diagnosed by observing a failure to heal rather than a clinical exacerbation. Due the presence of Triethanolamine 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.

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

Acute: Eye contact may cause irritation. May be harmful if swallowed.

Chronic: Prolonged or repeated skin contact may cause stinging, burning, itching, and irritation. Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis and other symptoms described earlier in this Section.

TARGET ORGANS:

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

Chronic: Occupational Exposure: Skin. *Therapeutic Doses:* Skin, endocrine system, blood system, bones, pituitaryadrenal, urinary, and cardiovascular systems. Potential fetal harm.

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 in this SDS; Contact Fougera for more information.

HYDROCORTISONE:

Standard Draize Test (Skin-Woman) 1%: Moderate
Standard Draize Test (Skin-Human) 0.5%/2 days
TDLo (Oral-Human) 1.43 mg/kg: Cardiac: change in rate; Endocrine: other changes
TDLo (Oral-Human) 0.429 mg/kg: Brain and Coverings: changes in surface EEG; Behavioral: changes in psychophysiological tests
TDLo (Oral-Human-Man) 400 mg/kg/10 days-intermittent: Behavioral-changes in psychophysiological tests
TDLo (Oral-Human-Man) 1.43 mg/kg: Vascular: other changes
TDLo (Oral-Human-Man) 1.4 mg/kg: Behavioral: changes in psychophysiological tests
TDLo (Oral-Human-Man) 0.71 mg/kg: Behavioral: changes in psychophysiological tests; Lungs, Thorax, or Respiration: respiratory stimulation; Endocrine: other changes
TDLo (Oral-Human-Man) 0.29 mg/kg: Endocrine-other changes
TDLo (Intravenous-Human) 0.5 mg/kg: Behavioral: anti-anxiety; Vascular: BP lowering not characterized in autonomic section
TDLo (Intravenous-Human-Woman) 50 mg/kg/5 days-continuous: Behavioral: convulsions or effect on seizure threshold
TDLo (Intravenous-Human-Man) 1 mg/kg: Brain and Coverings: changes in surface EEG; Behavioral: changes in REM sleep (human); Endocrine: other changes
TDLo (Unreported- Human-Man) 5.71 mg/kg/5 days-intermittent: Vascular: BP elevation not characterized in autonomic section
TDLo (Unreported- Human-Man) 1.14 mg/kg: Vascular: BP elevation not characterized in autonomic section
LD_{50} (Oral-Rat) 5000 mg/kg
LD_{50} (Oral-Rat) 600 mg/kg/10 days-intermittent: Brain and Coverings: other degenerative changes
LD_{50} (Oral-Mouse) 5000 mg/kg
LD_{50} (Administration onto the skin-Mouse) 23 mg/kg
LD_{50} (Subcutaneous-Rat) 449 mg/kg: Nutritional and Gross Metabolic: weight loss or decreased weight gain
LD_{50} (Subcutaneous-Mouse) > 500 mg/kg
LD_{50} (Intraperitoneal-Rat) 150 mg/kg: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
LD_{50} (Inhalation-Rat) 31 mg/m3: Liver: other changes; Kidney/Ureter/Bladder: other changes
TDLo (Oral-Rat) 210 mg/kg: female 14 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina
TDLo (Oral-Mouse) 20 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (Oral-Mouse) 140 mg/kg/7 days-intermittent: Endocrine: changes in thymus weight; Nutritional and Gross Metabolic: weight loss or decreased weight gain; Related to Chronic Data: death
TDLo (Oral-Mouse) 10 mg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Administration onto the skin-Mouse) 8.7 mg/kg: Vascular: other changes; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Administration onto the skin-Mouse) 300 mg/kg/10 days-intermittent: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Intraperitoneal-Rat) 50 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

HYDROCORTISONE (continued):

TDLo (Intraperitoneal-Rat) 150 mg/kg/10 days-intermittent: Kidney/Ureter/Bladder: other changes in urine composition; Biochemical: Metabolism (Intermediary): amino acids (including renal excretion), (Intermediary): other
TDLo (Intraperitoneal-Rat) 80 mg/kg: female 14-15 day(s) after conception: Reproductive: Effects on Newborn: biochemical and metabolic
TDLo (Intraperitoneal-Mouse) 50 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (Intraperitoneal-Mouse) 25 mg/kg: Behavioral: analgesia; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Intraperitoneal-Mouse) 400 mg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue
TDLo (Subcutaneous-Rat) 175 mg/kg/85 days-intermittent: Endocrine: changes in adrenal weight; Nutritional and Gross Metabolic: weight loss or decreased weight gain
TDLo (Subcutaneous-Rat) 50 mg/kg: female 18 day(s) after conception: Reproductive: Effects on Newborn: biochemical and metabolic
TDLo (Subcutaneous-Rat) 330 mg/kg: female 1-22 day(s) after conception: Reproductive: Specific Developmental Abnormalities: endocrine system; Effects on Newborn: growth statistics (e.g.%, reduced weight gain)
TDLo (Subcutaneous-Rat) 200 mg/kg: female 14-15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Subcutaneous-Rat) 200 mg/kg: female 14-15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Subcutaneous-Rat) 220 mg/kg: female 9-19 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: endocrine system; Effects on Newborn: biochemical and metabolic
TDLo (Subcutaneous-Mouse) 62 mg/kg/11 days-intermittent: Endocrine: other changes
TDLo (Subcutaneous-Mouse) 560 mg/kg/2 weeks-intermittent: Liver: other changes; Blood: agranulocytosis, changes in bone marrow (not otherwise specified)
TDLo (Subcutaneous-Mouse) 100 mg/kg: female 10-13 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 400 mg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue
TDLo (Subcutaneous-Mouse) 100 mg/kg/4 days-intermittent: Liver: changes in liver weight
TDLo (Subcutaneous-Mouse) 156 mg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 200 mg/kg: female 12 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

HYDROCORTISONE (continued):

TDLo (Subcutaneous-Rabbit) 6 mg/kg: female 24-26 day(s) after conception: Reproductive: Effects on Newborn: other neonatal measures or effects, growth statistics (e.g.%, reduced weight gain)

TDLo (Intramuscular-Rat) 500 mg/kg: female 13 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Mouse) 400 mg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Mouse) 200 mg/kg: female 12 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death

TDLo (Intramuscular-Hamster) 150 mg/kg: female 12 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: craniofacial (including nose and tongue)

TDLo (Intramuscular-Hamster) 333 mg/kg: female 10 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)

TDLo (Intramuscular-Hamster) 400 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: cytological changes (including somatic cell genetic material); Specific Developmental Abnormalities: craniofacial (including nose and tongue)

HYDROCORTISONE (continued):

TDLo (Parenteral-Rat) 50 mg/kg: female 16-18 day(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo

TDLo (Parenteral-Rat) 35 mg/kg: female 7 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina

TDLo (Intraplacental-Mouse) 4 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death; Specific Developmental Abnormalities: other developmental abnormalities

TDLo (Ocular-Rabbit) 2945 µg/kg: female 6-18 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death

TDLo (Unreported-Rat) 100 mg/kg: Liver: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases

DNA Adduct (Human Liver) 2 mmol/L

DNA Adduct (Human Liver) 2 mmol/L/1 hour

DNA Adduct (Human Liver) 2 mmol/plate/1 hour

Unscheduled DNA Synthesis (Intraperitoneal-Rat) 20 mg/kg

DNA Inhibition (Intraperitoneal-Rat) 100 mg/kg

DNA Inhibition (Rat Mammary Gland) 1 mg/L

DNA Inhibition (Mouse Cells-Not Otherwise Specified) 100 nmol/L

DNA Inhibition (Intraperitoneal-Guinea Pig) 50 mg/kg

DNA Inhibition (Guinea Pig Lung) 1 mg/L

DNA Inhibition (Bird-Chicken Embryo) 450 pmol/L

Cytogenetic Analysis (Intraperitoneal-Mouse) 50 mg/kg

Unscheduled DNA Synthesis (Guinea Pig Lung) 1 mg/L

Unscheduled DNA Synthesis (Bird-Chicken Embryo) 10 mg/L

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

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

Excipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

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

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 Hydrocortisone have revealed negative results. No human data are available.

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: Long-term animal studies have not been performed to evaluate the effect on fertility of topical corticosteroids. 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.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for soil absorption or mobility. The following information is available for the components of this product:

HYDROCORTISONE: The Koc of hydrocortisone is estimated as 180, using a log Kow of 1.61 and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that hydrocortisone is expected to have moderate mobility in soil.

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

GLYCERIN: Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1,220,000 mg/L at 5°C, soil adsorption coefficients for Glycerin can be estimated at 3 and 2, respectively, using regression-derived equations. The magnitude of these values indicate that glycerin will display very high mobility in soil.

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

STEARYL ALCOHOL: The Koc of this compound is estimated as 1.8X10+5, using a water solubility of 1.1X10-3 mg/L at 25°C and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that this material is immobile in soil.

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

HYDROCORTISONE: If released to air, an estimated vapor pressure of 1.3X10-13 mm Hg at 25°C indicates Hydrocortisone will exist solely in the particulate phase in the atmosphere. Particulate-phase hydrocortisone will be removed from the atmosphere by wet or dry deposition. Hydrocortisone does not absorb at wavelengths > 290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight. If released to soil, Hydrocortisone is expected to have moderate mobility based upon an estimated Koc of 180. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 5.8X10-8 atm-cu m/mole. Biodegradation data were not available. If released into water, Hydrocortisone is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

12. ECOLOGICAL INFORMATION

PERSISTENCE AND BIODEGRADABILITY (continued):

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

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

ISOPROPYL PALMITATE: If released to air, an estimated vapor pressure of 5.6X10-5 mm Hg at 25°C indicates Isopropyl Palmitate will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase Isopropyl Palmitate will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 17 hours. Particulate-phase Isopropyl Palmitate will be removed from the atmosphere by wet and dry deposition. If released to soil, Isopropyl Palmitate is expected to have no mobility based upon an estimated Koc of 52,000. Volatilization from moist soil surfaces is expected to be an important fate process based upon an estimated Henry's Law constant of 0.016 atm-cu m/mole. However, adsorption to soil is expected to attenuate volatilization. Isopropyl Palmitate is expected to rapidly biodegrade in aerobic soils as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. If released into water, Isopropyl Palmitate is expected to adsorb to suspended solids and sediment in the water column based upon the estimated Koc. Isopropyl Palmitate is expected to rapidly biodegrade in aerobic waters as suggested by the rapid biodegradation of structurally similar long-chain fatty acid esters. Volatilization from water surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 5 hours and 7 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column. The volatilization half-life from a model pond is estimated to be about 61 hours ignoring adsorption; when considering maximum adsorption the volatilization half-life increases to 15 months. An estimated BCF of 53 suggests the potential for bioconcentration in aquatic organisms is moderate. An estimated base-catalyzed second-order hydrolysis rate constant of 0.021 L/mole-sec corresponds to half-lives of 10 and 1 years at pH values of 7 and 8, respectively.

STEARYL ALCOHOL: Based on a classification scheme, an estimated Koc value of 1.8X10+5, determined from a water solubility of 1.1X10-3 mg/L and a regression-derived equation, indicates that this compound is expected to be immobile in soil. Volatilization of This material from moist soil surfaces may be expected to be an important fate process given an estimated Henry's Law constant of 8.41X10-4 atm-cu m/mole, derived from a vapor pressure of 2.7X10-6 mmHg at 25°C, and its water solubility. However, adsorption to soil is expected to attenuate volatilization. This material is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Biodegradation of this compound may be an important fate process in soil based on a mixed shake flask culture study. Based on a classification scheme, an estimated Koc value of 1.8X10+5, determined from a water solubility of 1.1X10-3 mg/L and a regression-derived equation, indicates that This compound is expected to adsorb to suspended solids and sediments. Volatilization from water surfaces is expected based upon an estimated Henry's Law constant of 8.4X10-4 atm-cu m/mole, calculated from its water solubility and vapor pressure, 2.7X10-6 mmHg, values. Using this Henry's Law constant and an estimation method, volatilization half-lives for a model river and model lake are 2.8 hours and 7 days, respectively. However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column. A percent theoretical oxygen demand value of 0.3 in 24-hrs using a Warburg test suggests that biodegradation may not be an important fate process in water. According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, this material, which has a vapor pressure of 2.7X10-6 mm Hg at 25°C, will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be about 14 hours, calculated from its rate constant of 2.67X10-11 cu cm/molecule-sec at 25°C that was derived using a structure estimation method. Particulate-phase material may be removed from the air by wet or dry deposition. Using the Warburg test which employs activated sludge, this compound gave a theoretical oxygen demand of 0.3, 0.5, and 0.3 percent in 6, 12, and 24 hours. However, using an acclimated mixed shake flask culture with incremental substrate addition of this material, biomass yield reached 54.5 percent after seven days. Given sufficient time in contact with adapted microbial species under conditions otherwise non-limiting, the complete disappearance of this compound as identifiable molecular species will occur.

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

HYDROCORTISONE: An estimated BCF of 3 was calculated in fish for this compound, using a log Kow of 1.61 and a regression-derived equation. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is low.

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

GLYCERIN: Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1,220,000 mg/L at 5°C, bioconcentration factors for Glycerin can be estimated at 3 and 0.2, respectively, using regression-derived equations. The magnitude of these values indicate that bioconcentration of Glycerin in fish and aquatic organisms will not be significant. Log K_{OW} = -1.76.

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

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

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

BENZYL ALCOHOL:

LC_{50} (*Pimephales promelas* fathead minnows) 96 hours = 460 mg/L (static bioassay in Lake Superior water at 18-22°C)

LC_{50} (*Lepomis macrochirus* bluegill sunfish) 96 hours = 10 ppm/L (static bioassay in fresh water at 23°C, mild aeration after 24 hours)

LC_{50} (*Medina beryllina* tidewater silverside fish) 96 hours = 15 ppm (static bioassay in synthetic seawater at 23°C, mild aeration after 24 hours)

LC_{50}, S (*Medina beryllina* tidewater silverside fish) 96 hours = 15 mg/L

LC_{50} (*Daphnia*) 24 hours = 55; 400 mg/L

LC_{50} (*Petromyzon marinus* larvae) 24 hours = >5 mg/L

EC_{50} (*Photobacterium phosphoreum*) 30 minutes = 71 mg/L

EC_{50} (*Scenedesmus quadricauda*) 3 hours = 79 mg/L

EC_{50} (*Haematococcus pluvialis*) 4 hours = 2,600 mg/L

EC_{50} (*Anabaena cylindrica*) 3 hours = 90 mg/L

BENZYL ALCOHOL (continued):

EC_{50} (*Anabaena variabilis*) 3 hours = 35 mg/L

EC_{50} (*Chlorella pyrenoidosa*) 3 hours = 95 mg/L

GLYCERIN:

Toxicity threshold (cell multiplication inhibition test) Algae (Microcystis aeruginosa) = 2900 mg/L

Toxicity threshold (cell multiplication inhibition test) Protozoa (Entosiphon sulcatum) = 3200 mg/L

LC_{50} (Goldfish) 24 hours = > 5000 mg/L/modified ASTM D 1345

STEARYL ALCOHOL:

NOEC (*Streptococcus mutans* bacteria) 24 hours = >3.3 mg/L

NOEC (*Candida albicans* fungi) 30 hours = 10 g/L

NOEC (*Mucor mucedo* fungi) 30 hours = 10 g/L

NOEC (*Trichophyton mentagrophytes* fungi) 5 days = 10 g/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.

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

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

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): Not applicable.

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

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

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.

15. REGULATORY INFORMATION (Continued)

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 BE HARMFUL IF SWALLOWED. PROLONGED SKIN CONTACT MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE EYE IRRITATION. MAY CAUSE ALLERGIC SKIN REACTION. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY. COMBUSTIBLE-MAY IGNITE IF HIGHLY HEATED FOR A PROLONGED PERIOD. 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.

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:

Hydrocortisone Acetate: This is a self-classification.
Classification: Reproductive Toxicity Category 2, Skin Irritation Category 2, Acute Oral Toxicity Category 5, Acute Inhalation Toxicity Category 5, Acute Dermal Category 5, Skin Sensitization Category 1B
Hazard Statement Codes: H361d: Suspected of damaging the unborn child. H315: Causes skin irritation. H303 + H313 + H333: May be harmful if swallowed, in contact with skin or if inhaled. H317: May cause an allergic skin reaction.

Benzyl Alcohol: This is a published classification.
Classification: Acute Oral Category 4, Acute Inhalation Category 4
Hazard Statement Codes: H312 + H332: Harmful in contact with skin or if inhaled.

Isopropyl Palmitate: This is a self-classification.
Classification: Skin Irritation Category 3
Hazard Statement Codes: H316: Causes mild skin irritation.

Polyoxyl 40 Stearate: This is a self-classification.
Classification: Skin Irritation Category 2, Eye Irritation Category 2A, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3
Hazard Statement Codes: H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

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

Full Text EU 67/548/EEC:

Hydrocortisone: This is a self-classification.
Classification: Reproductive Toxicity Category 3, Irritant
Risk Phrases: R63: Possible risk of harm to the unborn child. R38: Irritating to skin. R43: May cause sensitisation by skin contact.

Benzyl Alcohol: This is a published classification.
Classification: Harmful
Risk Phrases: R20/22: Harmful by inhalation and if swallowed.

Isopropyl Palmitate: This is a self-classification.
Classification: Irritant
Risk Phrases: R38: Irritating to skin.

Polyoxyl 40 Stearate: This is a self-classification.
Classification: Irritant
Risk Phrases: R36/37/38: Irritating to eyes, respiratory system and skin.

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

REVISION DETAILS: April 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.

16. OTHER INFORMATION (Continued)

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.

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DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

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

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.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued):***1* (continued):** *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).

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.

DEFINITION OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

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

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

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

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **4 (continued):** 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.

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.

DEFINITION OF TERMS (Continued)

TOXICOLOGICAL INFORMATION:

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

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

REPRODUCTIVE TOXICITY INFORMATION:

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

ECOLOGICAL INFORMATION:

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

REGULATORY INFORMATION:

U.S.:

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

CANADA:

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

REVISION HISTORY

Date	**Changes**
September 6, 2015	Update CHEMTEL number.
August 6, 2015	Correction to description (lotion to cream), correction to information of ingredients (added 0.5% to active pharmaceutical ingredient).
May 30, 2015	Change emergency phone number to Chemtel.
April 21, 2014	Up-date to add GHS & EU compliance.
November 26, 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.