SAFETY DATA SHEET

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 Lotion |
| 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): | Corticosteroid |
| CHEMICAL FAMILY (for active ingredient): | Hydrocortisone [pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-,(11β,)] |
| HOW SUPPLIED: | Lotion |
| 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): | 1-800-424-9300 (24-hr) |
| EMERGENCY PHONE (OUTSIDE U.S.): | +1-631-454-7677 |

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

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


EMERGENCY OVERVIEW: Product Description: This product is a 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. 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

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>LABEL ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone</td>
<td>50-23-7</td>
<td>200-020-1</td>
<td>1.0 and 2.5%</td>
<td>EU 67/548, Classification: Reproductive Toxicity Cat. 3, Harmful, Irritant, Risk Phrases: R63, R38, R43, Hazard Symbol: XnXi</td>
</tr>
<tr>
<td>Preg-n-4-ene-3,20-dione,11,17,21-trihydroxy-,(11β)</td>
<td></td>
<td></td>
<td></td>
<td>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</td>
</tr>
</tbody>
</table>

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

HYDROCORTISONE CREAM 0.5%, 1.0% and 2.5% SDS

EFFECTIVE DATE: APRIL 21, 2014

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3. COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>% w/w</th>
<th>EU Classification (67/548/EEC)</th>
<th>GHS &amp; EU Classification (1272/2008 EC)</th>
<th>Risk Phrases/Hazard Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzy l Alcohol</td>
<td>100-51-6</td>
<td>200-289-5</td>
<td>Proprietary</td>
<td>EU 67/548 Classification: Harmful</td>
<td>GHS &amp; EU 1272/2008 Classification: Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>200-282-5</td>
<td>Proprietary</td>
<td>EU 67/548 Classification: Not applicable.</td>
<td>GHS &amp; EU 1272/2008 Classification: Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Glyceryl Monostearate</td>
<td>123-94-4</td>
<td>204-664-3</td>
<td>Proprietary</td>
<td>EU 67/548 Classification: Not applicable.</td>
<td>GHS &amp; EU 1272/2008 Classification: Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Isopropyl Palmitate</td>
<td>142-91-6</td>
<td>205-571-1</td>
<td>Proprietary</td>
<td>SELF CLASSIFICATION</td>
<td>GHS &amp; EU 1272/2008 Classification: Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Polyoxyl 40 Stearate</td>
<td>9004-99-3</td>
<td>Not Listed</td>
<td>Proprietary</td>
<td>SELF CLASSIFICATION</td>
<td>GHS &amp; EU 1272/2008 Classification: Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>204-017-6</td>
<td>Proprietary</td>
<td>EU 67/548 Classification: Not applicable.</td>
<td>GHS &amp; EU 1272/2008 Classification: Not applicable.</td>
<td></td>
</tr>
<tr>
<td>Water and other trace components of less than 1% concentration</td>
<td>Proprietary</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 Static Discharge: Not sensitive.

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.

HYDROCORTISONE CREAM 0.5%, 1.0% and 2.5% SDS

EFFECTIVE DATE: APRIL 21, 2014
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. Rinse with clean water. Cleaning non-disposable equipment may result in rounded residual product; therefore, empty containers should be handled with care and 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:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS #</th>
<th>EXPOSURE LIMITS IN AIR</th>
<th>ACGIH-TLVs</th>
<th>OSHA-PRLS</th>
<th>NIOSH-RELs</th>
<th>NIOSH</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
<td>TWA mg/m³</td>
<td>STEL mg/m³</td>
</tr>
<tr>
<td>Hydrocortisone Acetate</td>
<td>50-23-7</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>NE</td>
<td>NE</td>
<td>Mist: 15 (total dust), 5 (resp. fract.)</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Glyceryl Monostearate</td>
<td>1233-39-6</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>Carcinogen: TLV-A4</td>
</tr>
<tr>
<td>Polyoxy 40 Stearate, Sorbitan Monostearate</td>
<td>1233-94-4</td>
<td>10</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td></td>
</tr>
<tr>
<td>Exposure limits given are for stearates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin</td>
<td>64742-43-4</td>
<td>2</td>
<td>NE</td>
<td>NE</td>
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<td>NE</td>
<td>NE</td>
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<tr>
<td>Exposure limits given are for paraffin wax fume</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Stearyl Alcohol</td>
<td>112-92-5</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE = Not Established. See Section 16 for Definitions of 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, inh, 2011
- Korea: TWA = 10 mg/m³ (mist), 2006
- Mexico: TWA = 10 mg/m³ (inhalable), 2004

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


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.
MOLECULAR WEIGHT: Mixture.
COLOR: White to off-white.
ODOR: Mildly fatty.
ODOR THRESHOLD: Not established.
BOILING POINT: 135°C (275°F)
EVAPORATION RATE (nBuAc = 1): Not available.
VAPOR PRESSURE (air = 1): Not established.
ODOR THRESHOLD: Not established.
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 acneform 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-pituitary-adrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine. 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.

HYDROCORTISONE CREAM 0.5%, 1.0% and 2.5% SDS

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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 prickle heat may occur. Symptoms of chronic skin absorption exposure may include reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine.

IRRITATION 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.


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

HYDROCORTISONE (continued):

- 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-Mouse) 1.43 mg/kg: Vascular: other changes
- TDL0 (Oral-Human-Man) 1.4 mg/kg: Behavioral: changes in psychophysiological tests
- TDL0 (Oral-Man) 0.71 mg/kg: Behavioral: changes in psychophysiological tests; Lungs, Thorax, or Respiration: respiratory stimulation; Endocrine: other changes
- TDL0 (Oral-Human-Man) 0.29 mg/kg: Endocrine-other changes
- TDL0 (Intraocular-Human) 0.5 mg/kg: Behavioral: anti-anxiety; Vascular: BP lowering not characterized in autonomic section
- TDL0 (Intraocular-Human-Woman) 50 mg/kg/5 days-continuous: Behavioral: correlations or effects on seizure threshold
- TDL0 (Intraocular-Human-Man) 1 mg/kg: Brain and Coverings: changes in surface EEG; Behavioral: changes in REM sleep (human); Endocrine: other changes
- TDL0 (Unreported: Human-Man) 5.71 mg/kg; 35 days-intermittent: Vascular: BP elevation not characterized in autonomic section
- TDL0 (Unreported: Human-Man) 1.14 mg/kg: Vascular: BP elevation not characterized in autonomic section
- LDe (Oral-Rat) 5000 mg/kg
- LDe (Oral-Rat) 600 mg/kg/10 days-intermittent: Brain and Coverings: other degenerative changes
- LDe (Oral-Mouse) 5000 mg/kg
- LDe (Administration onto the skin-Mouse) 23 mg/kg
- LDe (Subcutaneous-Rat) 449 mg/kg: Nutritional and Gross Metabolism: weight loss or decreased weight gain
- LDe (Subcutaneous-Mouse) > 500 mg/kg
- LDe (Intraperitoneal-Rat) 150 mg/kg: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
- LDe (Inhalation-Rat) 31 mg/m3; Liver: other changes; Kidney/Ureter/Bladder: other changes
- TDL0 (Oral-Rat) 210 mg/kg; female 14 day(s)-pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina
- TDL0 (Oral-Mouse) 20 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
- TDL0 (Oral-Mouse) 100 mg/kg; 35 days-intermittent: Endocrine: changes in thymus weight; Nutritional and Gross Metabolism: weight loss or decreased weight gain; Related to Chronic Data: death
- TDL0 (Administration onto the skin-Mouse) 8.7 mg/kg: Vascular: other changes; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
- TDL0 (Administration onto the skin-Mouse) 300 mg/kg/10 days-intermittent: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
- TDL0 (Intraperitoneal-Rat) 50 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDL0 (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

- TDL0 (Intraperitoneal-Rat) 80 mg/kg/ female 14-15 day(s) after conception: Reproductive: Effects on Newborn: biochemical and metabolic
- TDL0 (Intraperitoneal-Mouse) 50 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
- TDL0 (Intraperitoneal-Mouse) 25 mg/kg: Behavioral: analgesia; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

- TDL0 (Intraperitoneal-Mouse) 40 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)
- TDL0 (Subcutaneous-Rat) 175 mg/kg/85 days-intermittent: Endocrine: changes in adrenal weight; Nutritional and Gross Metabolic: weight loss or decreased weight gain
- TDL0 (Subcutaneous-Rat) 50 mg/kg/ female 18 day(s) after conception: Reproductive: Effects on Newborn: biochemical and metabolic
- TDL0 (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)
- TDL0 (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)
- TDL0 (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)
- TDL0 (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
- TDL0 (Subcutaneous-Mouse) 62 mg/kg/11 days-intermittent: Endocrine: other changes
- TDL0 (Subcutaneous-Mouse) 560 mg/kg/ 2 weeks-intermittent: Liver: other changes; Blood: agranulocytosis, changes in bone marrow (not otherwise specified)
- TDL0 (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)
- TDL0 (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)
- TDL0 (Subcutaneous-Mouse) 156 mg/kg/ female 12 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TOXICITY DATA (continued):

**HYDROCORTISONE (continued):**
- **TDLo (Parenteral-Rat)** 50 mg/kg: female 16-18 days after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo
- **TDLo (Parenteral-Rat)** 35 mg/kg: female 7 days (pre-mating): Reproductive: Maternal Effects: uterus, cervix, vagina

**GLYCERYL MONOSTEARATE:**
- **GLYCERYL MONOSTEARATE:**

**POLYOXYL 40 STEARATE:**
- **POLYOXYL 40 STEARATE:**

**SORBITAN MONOSTEARATE:**
- **SORBITAN MONOSTEARATE:**

**ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)**

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.

Excipt 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 sorption 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.

**ACYL 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.
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 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-cm/mole. Benzyl Alcohol is not expected to volatilize rapidly from dry soil surfaces based upon its vapor pressure. Benzyl Alcohol is expected to adsorb to suspended solids and sediment in 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 has no 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 in fish and aquatic organisms nor is it expected to adsorb its 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 soil surfaces is expected to be an important fate process based upon an 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 on the order of days. Based on a classification scheme, this BCF 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 1.8X10^4 is expected, derived from a water solubility of 1.1X10^-3 mg/L and a regression-derived equation. This compound is expected to be immobile in soil. Volatilization of this material from soil surfaces may be expected to be an important fate process given an estimated Henry's Law constant of 8.4X10^4 atm-cm/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 rapid from dry soil surfaces based upon its estimated LC50 value of 1.8X10^4 mg/L and a regression-derived equation, indicating that this compound is expected to be adsorbed to suspended solids and sediments. Volatilization from water surfaces is expected based upon an estimated Henry's Law constant of 8.4X10^4 atm-cm/mole, calculated from its water solubility and vapor pressure, 2.7X10^-6 mmHg, vapour pressure, and its 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 demand 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 ambient 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 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 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 in 4 days, 0.3 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.

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

LC50 (Pimephales promelas fathead minnows) 96 hours = 460 mg/L (static bioassay in Lake Superior water at 18-22°C)
LC50 (Lepomis macrochirus bluegill sunfish) 96 hours = 10 ppm (static bioassay in fresh water at 23°C, mild aeration after 24 hours)
LC50 (Medina beryllia tidewater silverside fish) 96 hours = 15 ppm (static bioassay in synthetic seawater at 5°C, mild aeration after 24 hours)
LC50 (S (Medina beryllia tidewater silverside fish) 96 hours = 15 mg/L
LC50 (Daphnia) 24 hours = 55; 400 mg/L
LC50 (Petrovemnus marinus larvae) 24 hours = >5 mg/L
EC50 (Photobacterium phosphoreum) 30 minutes = 71 mg/L
EC50 (Scedesmus quadricauda) 3 hours = 79 mg/L
EC50 (Hemiascomus plusulva) 4 hours = 2,600 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
Toxicity threshold (cell multiplication inhibition test) Test protocols (Entosiphon sulcatum) = 3200 mg/L

BENZYL ALCOHOL (continued):

EC50 (Arabana variabilis) 3 hours = 35 mg/L
EC50 (Chlorella pyrensosida) 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

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: Strategies 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. Ensure that any required marking or labeling of the containers be done to all applicable regulations. 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.

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, CO₂, or “alcohol” foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

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


CLASSIFICATION FOR COMPONENTS:
Full Text 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 Toxicity Category 5, Skin Sensitization Category 1B
  - **Hazard Statement Codes**:
    - 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 3
  - **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**: Hazardous
  - **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.
A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

Hazardous Materials Identification System Hazard Ratings (continued):

- *Flammable Hazard:* Oral Toxicity LD₅₀ Rat: > 500–5000 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: > 1000–2000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: > 2–20 mL/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 ≤ 8. 3 Moderate Hazard: Temporarily or reversibly irritating; corneal irritation clearing in ≤ 8 days. Skin Irritation: Severe, irreversible; corrosive; may cause destruction of topical dermal tissue, skin burns, and dermal necrosis. PII or Draize: ≥ 8–9, with destruction of tissue. Eye Irritation: Corrosive. 4 Severe Hazard: Life-threatening; severe irritation or damage; may result from exposure 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 IIB); 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 dust that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a crepated form that may burn rapidly forming a fire (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 may ignite 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: Materials having a flash point at or above 5°C (41°F) and having a boiling point at or above 38°C (100°F) or 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 atmospheres 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 IB and IC). Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric). 4 Severe Hazard: 0 Water Reactivity: Materials that do not react with water. 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: Compressed gases that do not exceed the following criteria: LD₅₀ Rat or Rabbit: > 2000 mg/kg. Dermal Toxicity LD₅₀ Rat or Rabbit: > 2000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat or Rabbit: > 20 mL/L. 1 Slight Hazard: Minor reversible injury may occur; may irritate the stomach if swallowed; may irritate the skin and exacerbate existing dermatological skin irritation. Slightly or mildly irritating. PII or Draize: > 0–5. 1 Slight Hazard: Slightly to mildly irritating, but reversible within 7 days. Draize: > 0–5.
HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

DESCRIPTION OF TERMS (continued):

1. Unstable Reactives: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, and have a low potential (or risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. 

2. Water Reactivity: Materials that react explosively with water, and the criteria for Packing Group I are not met. Reactive: Substances that may polymerize, decompose, or self-react at ambient temperature and/or pressure and have a low potential (or risk) for significant heat generation or explosion. 

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD: 0 Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC₅₀ for acute inhalation toxicity greater than 200 mg/L. Materials with an LD₅₀ for acute oral toxicity greater than 2000 mg/kg. Materials with an LC₅₀ for acute dermal toxicity greater than 200 mg/kg. 

1. Dusts and mists with an aerosol concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, but less than or equal to 10 mg/L. Materials with an LC₅₀ for acute dermal toxicity greater than 500 mg/kg but less than or equal to 10 mg/kg. 

2. Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC₅₀ for acute inhalation toxicity greater than 3000 ppm but less than or equal to 5000 ppm. 

3. Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC₅₀ for acute inhalation toxicity greater than 5000 ppm but less than or equal to 10000 ppm. 

4. Materials that, under emergency conditions, are capable of being ingested without a protective mask. 

FLAMMABILITY HAZARD: 0 Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. 

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). Flammability limits in air are denoted by the minimum concentration of flammable vapor or gas required to sustain combustion when tested using the Method of Testing for Sustained Combustibility, per NFPA 49, Appendix H or the UN Recommendations on the Transport of Dangerous Goods: Recommendations (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solvent or dispersion with a water non-combustible liquid/solid content of more than 50% by weight, or 40% by volume, in the event of accidental release.
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. LD₅₀: Lethal Dose (solids & liquids) that kills 50% of the exposed animals. LC₅₀: Lethal Concentration (gases) expressed in parts of material per million parts of air or water. mg/m³: Concentration expressed in weight of substance per volume of air. mg/kg: Quantity of material, by weight, administered to a test subject, based on their body weight in kg. TDₕ₀: Lowest dose to cause a symptom. TCL₀: Lowest concentration to cause a symptom. TD₆₀, TCL₀, LD₆₀, and TCL₀: 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 Kₐw or log Kₐc: 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:
<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
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<tbody>
<tr>
<td>November 26, 2011</td>
<td>Company name change correction. Change of heading text, Section 5. Review and up-date of exposure limits to current, Section 8. Change text on Reproductive Toxicity, Section 11. Revision to Definition of Terms. Up-date Section 12. Revise Canadian WHMIS status. Move ANSI Labeling to Section 16. Add revision history section.</td>
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<tr>
<td>April 21, 2014</td>
<td>Up-date to add GHS &amp; EU compliance.</td>
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