Nycomed US Inc.

MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, and Canadian WHMIS

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

1. PRODUCT IDENTIFICATION

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

DESCRIPTION:	Hydrocortisone Cream
NDC #:	0168-0014-31; 0168-0154-08; 0168-0154-31; 0168-0015-16; 0168-0015-31; 0168-0080-16; 0168-0080-31
CHEMICAL NAME (for active ingredient):	Hydrocortisone [pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11β,)]
CHEMICAL FAMILY (for active ingredient):	Corticosteroid
HOW SUPPLIED:	0.5%, 1.0%, and 2.5% Cream
FORMULA (for active ingredient):	$C_{21}H_{30}O_5$
PRODUCT USE:	Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER'S NAME:	**NYCOMED US INC.**
ADDRESS:	60 Baylis Road Melville, NY 11747
BUSINESS PHONE/GENERAL MSDS INFORMATION:	1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico):	**1-800-424-9300 (24-hrs)**
EMERGENCY PHONE (OUTSIDE U.S.):	**+1-631-454-7677**

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian WHMIS [Controlled Products Regulations] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: ***Product Description:*** This product is a white cream with a slightly fatty odor. ***Health Hazards:*** The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing the active ingredient, Hydrocortisone, or any other components of this product may experience allergic reactions to this product. Repeated skin exposure to Corticosteroids (such as Hydrocortisone) may cause adverse reproductive effects, based on animal data. ***Flammability Hazards:*** If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides). ***Reactivity Hazards:*** This product is not reactive. ***Environmental Hazards:*** This product has not been tested for environmental effects. ***Emergency Considerations:*** Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/w
Hydrocortisone	50-23-7	0.5%, 1.0%, and 2.5%
Isopropyl Palmitate	142-91-6	Proprietary
Sorbitan Monostearate	1338-41-6	Proprietary
Stearyl Alcohol	112-92-5	Proprietary
Benzyl Alcohol	100-51-6	Proprietary
Paraffin	64742-43-4	Proprietary
Glycerin	56-81-5	Proprietary
Polyoxyl 40 Stearate	9004-99-3	Proprietary
Glyceryl Monostearate	123-94-4	Proprietary
Water and other components. Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).	The remaining components do not contribute any significant additional hazards.	Balance

Nycomed US Inc.

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

4 FIRST-AID MEASURES

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

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

EYE EXPOSURE: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

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

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

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

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

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable. *Upper (UEL):* Not applicable.

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

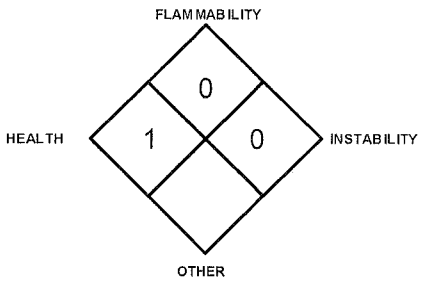
Water Spray: OK *Carbon Dioxide:* OK
Foam: OK *Dry Chemical:* OK
Halon: OK *Other:* Any "ABC" Class

FIRE EXTINGUISHING MATERIALS NOT TO BE USED: None known.

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

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



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

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

6. ACCIDENTAL RELEASE MEASURES

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

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

6. ACCIDENTAL RELEASE MEASURES (Continued)

SPILL AND LEAK RESPONSE (continued):

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

Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

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

7. HANDLING and USE

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

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

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

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

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

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

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Hydrocortisone	50-23-7	NE	NE	NE	NE	NE	NE	NE	NE
Isopropyl Palmitate	142-91-6	NE	NE	NE	NE	NE	NE	NE	NE
Sorbitan Monostearate (Exposure limits are for Stearates)	1338-41-6	10	NE	NE	NE	NE	NE	NE	NE
Stearyl Alcohol	112-92-5	NE	NE	NE	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEELs: TWA = 10 ppm
Paraffin	64742-43-4	NE	NE	NE	NE	NE	NE	NE	NE
Glycerin	56-81-5	10 (mist)	NE	15 (Total dust) 5 (Resp. fraction) 10 (Total) 5 (Resp. fraction) [vacated 1989 PEL]	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable fraction) PEAK = 2•MAK 15 min, average value, 1-hr interval DFG MAK Pregnancy Risk Classification: C

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES (continued):

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
Polyoxyl 40 Stearate (Exposure limits are for Stearates)	9004-99-3	10	NE	NE	NE	NE	NE	NE	NE
Glyceryl Monostearate (Exposure limits are for Stearates)	123-94-4	10	NE	NE	NE	NE	NE	NE	NE

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

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

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

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

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

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

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: 135°C (275°F)
EVAPORATION RATE (nBuAc = 1): 0.07
VAPOR PRESSURE (air = 1): Not established.
ODOR THRESHOLD: Not established.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
FREEZING/MELTING POINT: 60°C (140°F)
SOLUBILITY IN WATER: Soluble.
SPECIFIC GRAVITY (water = 1): Not established.
pH: Not established.

APPEARANCE AND COLOR: This product is a white cream with a slightly fatty odor.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

10. STABILITY and REACTIVITY

STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides).

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

HAZARDOUS POLYMERIZATION: Will not occur.

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

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

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

11. TOXICOLOGICAL INFORMATION (Continued)

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

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

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.

INJECTION: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for "General Toxicity Information".

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing the Hydrocortisone component of this product or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

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

For Males and Females: Persons using the product in therapeutic doses may experience burning, itching, irritation, dryness, inflammation of hair follicles, excessive growth of hair, acne-form eruptions, diminished pigmentation, dermatitis around the mouth, allergic contact dermatitis, softening of the skin, secondary infections, skin atrophy, striae, and prickly heat.

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

SENSITIZATION OF PRODUCT: Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis. The Benzyl Alcohol component of this product is a weak skin sensitizer; skin contact may cause an allergic reaction in sensitive individuals.

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

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Accidental ingestion may be harmful. Although unlikely, inhalation can irritate the respiratory system. Eye contact will cause irritation.

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

TARGET ORGANS:

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

Chronic: Occupational Exposure: Skin. *Therapeutic Doses:* Skin, endocrine system, blood system, bones, pituitaryadrenal system, urinary system, cardio-vascular system.

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

HYDROCORTISONE:
Standard Draize Test (Skin-Rabbit) 1000 ppm: Mild
LD_{50} (Oral-Rat) 5120 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

HYDROCORTISONE (continued):
LD_{50} (Oral-Mouse) 6720 mg/kg: Sense Organs and Special Senses (Eye): ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

HYDROCORTISONE (continued):
LD_{50} (Intraperitoneal-Rat) 1420 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

HYDROCORTISONE (continued):

LD_{50} (Intraperitoneal-Mouse) 1660 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD_{50} (Subcutaneous-Rat) 3260 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD_{50} (Subcutaneous-Mouse) 1980 mg/kg: Eye: ptosis; Behavioral: changes in motor activity (specific assay); Lungs, Thorax, or Respiration: respiratory depression

LD_{50} (Subcutaneous-Dog) > 1 gm/kg

TDLo (Skin-Rat) 82,500 µg/kg: female 7-17 days after conception: Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: musculoskeletal system; Effects on Newborn: live birth index (measured after birth)

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

HYDROCORTISONE (continued):

TDLo (Skin-Dog) 18,200 µg/kg/91 days-intermittent: Endocrine: changes in adrenal weight; Blood: pigmented or nucleated red blood cells, changes in leukocyte (WBC) count

TDLo (Subcutaneous-Rat) 60 mg/kg/30 days-intermittent: Endocrine: changes in spleen weight; Blood: changes in leukocyte (WBC) count; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (Subcutaneous-Rat) 15,600 µg/kg/26 weeks-intermittent: Cardiac: changes in heart weight; Liver: changes in liver weight; Blood: changes in platelet count

TDLo (Subcutaneous-Rat) 5 mg/kg: female 7 days after conception: Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)

TDLo (Subcutaneous-Rat) 1100 µg/kg: female 7-17 days after conception: Reproductive: Musculoskeletal Developmental Abnormalities

HYDROCORTISONE (continued):

TDLo (Subcutaneous-Rat) 1296 µg/kg: male 9 weeks pre-mating female 2 weeks pre-mating: 7 days after conception: Reproductive: Fertility: pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)

TDLo (Subcutaneous-Rat) 440 µg/kg: female 7-17 days after conception: Reproductive: Effects on Newborn: physical

TDLo (Subcutaneous-Rabbit) 6500 µg/kg: female 6-18 days after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants), litter size (e.g. # fetuses per litter; measured before birth); Effects on Fetus: fetal death

TDLo (Subcutaneous-Rabbit) 1300 µg/kg: female 6-18 days after conception: Reproductive: Effects on Newborn: growth statistics (e.g.%, reduced weight gain)

TDLo (Subcutaneous-Rabbit) 6500 µg/kg: female 6-18 days after conception: Reproductive: Musculoskeletal Developmental Abnormalities

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

GLYCERYL MONOSTEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as Human Carcinogen);
POLYOXYL 40 STEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as Human Carcinogen);
SORBITAN MONOSTEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as 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: The active component of this product, Hydrocortisone, is rated as Pregnancy Category C (RISK CANNOT BE RULED OUT; Human evidence is lacking, but animal evidence is positive). Listed below is information concerning the effects of this compound on animal or human reproductive systems.

Mutagenicity: The components of this product are not reported to cause mutagenic effects in humans.

Embryotoxicity: Studies have not been performed to evaluate the embryotoxic effects of this product.

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.

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.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption or mobility. The following environmental data are available for the components of this product:

BENZYL ALCOHOL:

Terrestrial Fate: Based on a classification scheme, Koc values of less than 5 to 15, indicate that Benzyl Alcohol is expected to have very high mobility in soil. Volatilization of Benzyl Alcohol from moist soil surfaces is not expected to be an important fate process given an estimated Henry's Law constant of 3.1X10-7 atm-cu m/mole, derived from its vapor pressure of 0.094 mm Hg and water solubility of 42,000 mg/L. Benzyl Alcohol is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Benzyl Alcohol, present at 100 mg/L, reached 92-96% of its theoretical BOD in 2 weeks using an activated sludge inoculum at 30 mg/l and the Japanese MITI test, suggesting that biodegradation will occur in soil.

Aquatic Fate: Based on a classification scheme, measured Koc values of less than 5 to 15 indicates that Benzyl Alcohol is not expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is expected to occur slowly based upon an estimated Henry's Law constant of 3.1X10-7 atm-cu m/mole, derived from its vapor pressure of 0.094 mm Hg and water solubility of 42,000 mg/L. Using this Henry's Law constant and an estimation method, volatilization half-lives for a model river and model lake are 75 days and 2.2 years, respectively. According to a classification scheme, an estimated BCF of 1, from its log Kow of 1.1 and a regression-derived equation, suggests the potential for bioconcentration in aquatic organisms is low. Benzyl Alcohol is expected to undergo biodegradation under both aerobic and anaerobic conditions based on results from aqueous biodegradation tests.

Atmospheric Fate: According to a model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere, Benzyl Alcohol, which has a vapor pressure of 0.094 mm Hg at 25°C, is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase Benzyl Alcohol is 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, calculated from its rate constant of 2.3X10-11 cu cm/molecule-sec at 25°C.

Bioconcentration: 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.

12. ECOLOGICAL INFORMATION (Continued)

ENVIRONMENTAL STABILITY (continued):

GLYCERIN:

Persistence and Biodegradability: 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.

Bioconcentration: 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.

Soil Adsorption/Mobility: 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:

Persistence and Biodegradability: 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.

Persistence and Biodegradability (continued): 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.

Bioconcentration: 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.

Soil Adsorption/Mobility: 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:

Persistence and Biodegradability: Based on a classification scheme, an estimated Koc value of 1.8X10+5, determined from a water solubility of 1.1X10-3 mg/L and a regression-derived equation, indicates that Octadecanol is expected to be immobile in soil. Volatilization of Octadecanol from moist soil surfaces may be expected to be an important fate process given an estimated Henry's Law constant of 8.41X10-4 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. Octadecanol is not expected to volatilize from dry soil surfaces based upon its vapor pressure. Biodegradation of Octadecanol may be an important fate process in soil based on a mixed shake flask culture study. Based on a classification scheme, an estimated Koc value of 1.8X10+5, determined from a water solubility of 1.1X10-3 mg/L and a regression-derived equation, indicates that Octadecanol 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, Octadecanol, which has a vapor pressure of 2.7X10-6 mm Hg at 25°C, will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase Octadecanol is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be about 14 hours, 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 1-Octadecanol may be removed from the air by wet or dry deposition. Using the Warburg test which employs activated sludge, Octadecanol gave a theoretical oxygen demand of 0.3, 0.5, and 0.3 percent in 6, 12, and 24 hours. However, using an acclimated mixed shake flask culture with incremental substrate addition of 1-octadecanol, biomass yield reached 54.5 percent after seven days. Given sufficient time in contact with adapted microbial species under conditions otherwise non-limiting, the complete disappearance of 1-octadecanol as identifiable molecular species will occur.

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

Soil Adsorption/Mobility: The Koc of Octadecanol is estimated as 1.8X10+5, using a water solubility of 1.1X10-3 mg/L at 25°C and a regression-derived equation. According to a classification scheme, this estimated Koc value suggests that 1-octadecanol is immobile in soil.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: 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 plant and animal life, especially in large quantities.

EFFECT OF CHEMICAL ON AQUATIC LIFE: Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

BENZYL ALCOHOL:

LC_0 (*Scenedesmus quadricauda*) 96 hours = 640 ppm
LC_0 (*Lepomis macrochirus* bluegill sunfish) 24 hours = >5 mg/L
LC_0 (*Leuciscus idus*) 48 hours = 630 mg/L
LC_0 (*Salmo trutta*) 24 hours = >5 mg/L
LC_0 (*Carassius auratus*) 24 hours = > 5 mg/L
LC_0 (*Daphnia*) 48 hours = 369 ppm
LC_{50} (*Pimephales promelas* fathead minnows) 24 hours = 770 mg/L
LC_{50} (*Pimephales promelas* fathead minnows) 48 hours = 770 mg/L (static bioassay in Lake Superior water at 18-22°C)
LC_{50} (*Pimephales promelas* fathead minnows) 72 hours = 480 mg/L (static bioassay in Lake Superior water at 18-22°C)
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)

BENZYL ALCOHOL (continued):

LC_{50},S (*Lepomis macrochirus* bluegill sunfish) 96 hours = 10 mg/L
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
LC_{100} (*Daphnia*) 24 hours = 100 mg/L
EC_0 (*Daphnia*) 24 hours = 26; 300 mg/L
EC_0 (*Anabaena inaequalis*) 3 hours = 30 mg/L
EC_0 (*E. coli*) 48 hours = 1,000 mg/L
EC_{10} (*Pseudomonas putida*) 16 hours = 658 mg/L
EC_{50} (*Photobacterium phosphoreum*) 30 minutes = 71 mg/L
EC_{50} (*Photobacterium phosphoreum*) 5 minutes = 50 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
EC_{50} (*Anabaena variabilis*) 3 hours = 35 mg/L
EC_{50} (*Chlorella pyrenoidosa*) 3 hours = 95 mg/L

12. ECOLOGICAL INFORMATION (Continued)

EFFECT OF CHEMICAL ON AQUATIC LIFE (continued):

BENZYL ALCOHOL (continued):
(*Lepomis macrochirus* bluegill sunfish) static bioassay in fresh water at 23°C, mild aeration applied after 24 hours: 100% survival after 5 ppm/96 hours, 20% survival after 18 ppm/96 hours, 20% survival after 32 ppm/48hours
(*Menidia beryllina* tidewater silverside fish) : static bioassay in synthetic seawater at 23°C: mild aeration applied after 24 hours, 80% survival after 10 ppm/96 hours, 20% survival after 32 ppm/96 hours

GLYCERIN:
EC_0 (*Pseudomonas putida* bacteria) 16 hours = >10,000 mg/L
EC_0 (*Microcystis aeruginosa* algae) 8 days = 2,900 mg/L

GLYCERIN (continued):
EC_0 (*Scenedesmus quadricauda* green algae) 7 days = > 10,000 mg/L
EC_0 (*Entosiphon sulcatum* protozoa) 72 hours = 3,200 mg/L
EC_0 (*Uronema parduczi* Chatton-Lwoff protozoa) = > 10,000 mg/L
LC_{50} (goldfish) 24 hours = > 5,000 mg/

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

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

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

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHODS: It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

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

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

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

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

14. TRANSPORTATION INFORMATION

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

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

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

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

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

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

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

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

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **CAUTION!** MAY CAUSE ALLERGIC REACTION. MAY CAUSE SKIN AND EYE IRRITATION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.