SAFETY DATA SHEET

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

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

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: HYDROCORTISONE CREAM USP, 1.0%

DESCRIPTION: Hydrocortisone Topical Cream
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: Pregn-4-ene-3,20-dione,11,17,21- trihydroxy-,(11β)
CHEMICAL FAMILY: For Active Ingredient: Corticosteroid
FORMULA: For Active Ingredient: $C_{21}H_{30}O_5$
HOW SUPPLIED: 1.0% (10 mg) Hydrocortisone in 2 fl oz and 4 fl oz Lotion
OTHER DESIGNATIONS: NDC: 00472-0321-26: 10 mg Hydrocortisone in 28.4 g (1 oz) tube

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**Actavis, Inc.**
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NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the Global Harmonization Standard format.

DATE OF PREPARATION: September 10, 2015 **DATE OF REVISION:** New

2. HAZARDS IDENTIFICATION

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 white to off-white cream supplied in 1 fluid ounce.

Health Hazards: In the workplace, exposure via eye contact may cause irritation. Ingestion may be harmful. Inhalation is unlikely due to viscosity. Prolonged skin contact may cause redness or skin discomfort and systemic effects as described under therapeutic use. Skin contact may cause sensitization and allergic skin reactions. In therapeutic use, the most common adverse reactions reported have included burning, itching, irritation, dryness, infection in the hair follicles, abnormal hair growth, acne, hypopigmentation, small bumps around mouth, allergic contact dermatitis, tissue softening, secondary infection, skin atrophy, stripping of skin and sweat rash. Inhibition of bone formation, suppression of calcium absorption and delayed wound healing have been reported. Repeated skin exposure to corticosteroids (such as Hydrocortisone) may cause adverse reproductive effects, based on animal data. Limited evidence of harm to fetus, as a corticosteroid. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for information on other potential health hazards known from therapeutic use.

Reactivity Hazards: This product is not reactive.

Flammability Hazards: This product may be combustible and ignite if exposure to high temperature or direct flame for a prolonged period. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including acrolein, carbon, potassium and nitrogen oxides).

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS GHS Under U.S. OSHA & EU Classification (1272/2008 EC) Hazard Statement Codes
ACTIVE INGREDIENT				
Hydrocortisone Pregn-4-ene-3,20-dione,11,17,21- trihydroxy-,(11β)	50-23-7	200-020-1	1.0%	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 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
EXCIPIENTS				
Glycerin	56-81-5	200-289-5	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303
Glyceryl Stearate	11099-07-3	234-325-6	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Isopropyl Palmitate	142-91-6	205-571-1	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Lactic Acid	50-21-5	200-018-0	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 5, Acute Dermal Toxicity Cat. 5, Skin Irritation Cat. 2, Eye Damage Cat. 1B Hazard Statement Codes: H303 + H313, H315, H318
Paraffin	8002-74-2	232-315-6	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303
Polyoxyl 40 Stearate	9004-99-3	Not Listed	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Potassium Sorbate	24634-61-5	246-376-1	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Sorbitan Monostearate	1338-41-6	215-664-9	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Stearyl Alcohol	112-92-5	204-017-6	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Skin Irritation Cat. 2, Eye Irritation Cat. 2A, Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H315, H319, H303
Purified Water	7732-18-5	231-791-2	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable

See Section 16 for full classification information.

4. FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of SDS to physician or other health professional with victim(s).

Inhalation: If mists or sprays from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

Skin Exposure: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

Eye Exposure: If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

Ingestion Exposure: 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. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

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

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, 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. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to aminoglycosides or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

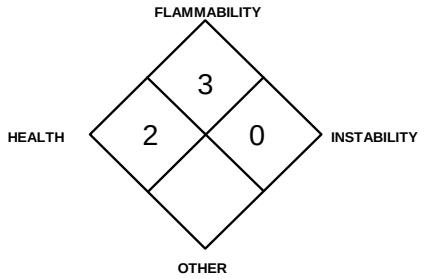
INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. Since there is no specific antidote available, treatment is symptomatic, supportive, and consists of discontinuance of topical corticosteroid therapy. Gradual withdrawal of the preparation may be necessary. For acute oral overdose: If ingested, serious adverse effects are unlikely, treatment consists of dilution with fluids.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.
AUTOIGNITION TEMPERATURE: Not established.
FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not determined.
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.
UNSUITABLE EXTINGUISHING MEDIA: None known.
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: This product may be combustible and ignite if exposure to high temperature or direct flame for a prolonged period. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., acrolein, carbon, potassium and nitrogen oxides).

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

NFPA RATING



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

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

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g. 1 tube), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. 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.**

METHODS FOR CLEANUP AND CONTAINMENT: Eliminate all sources of ignition before cleanup begins. Use non-sparking tools. In the event of a release of a large quantity of the gel, the appropriate personal protective equipment should be used**.**

Small Spills: Absorb up spilled material with damp sponge, polypads or other suitable material.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of mists or sprays onto polypads or other non-reactive absorption.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material 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.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing immediately. Keep away from heat, sparks, and other sources of ignition. Keep container tightly closed when not in use. Use non-sparking tools. Bond and ground containers during transfers of material. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.

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

7. HANDLING and USE (Continued)

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store at 2-30°C (35.6-86°F) and away from moisture, humidity and light. Material should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity). Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Material should be stored in secondary containers or in a diked area, as appropriate. Store containers away from incompatible chemicals (see Section 10, Stability and Reactivity). Containers should be separated from oxidizing materials by a minimum distance of 20 ft. or by a barrier of non-combustible material at least 5 ft. high having a fire-resistance rating of at least 0.5 hours. Storage areas should be made of fire resistant materials. Post warning and "NO SMOKING" signs in storage and use areas, as appropriate. Have appropriate extinguishing equipment in the storage area (i.e., sprinkler system, portable fire extinguishers). Inspect all incoming containers before storage to ensure containers are properly labeled and not damaged. Refer to NFPA 30, *Flammable and Combustible Liquids Code*, for additional information on storage. Empty containers may contain residual liquid or vapors which are flammable; therefore, empty containers should be handled with care.

SPECIFIC END USE(S): This product is a placebo for 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.

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.

Occupational/Workplace Exposure Limits/Guidelines: Note: Sodium Hydroxide and Citric Acid used to adjust the product pH. No residual remains and so no exposure limits are given for these compounds.

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA ppm	STEL ppm	TWA ppm	STEL ppm	TWA ppm	STEL ppm	IDLH ppm	ppm
Hydrocortisone	50-23-7	NE	NE	NE	NE	NE	NE	NE	Actavis OEL: 100 µg/m^3
Glycerin	56-81-5	NE	15 (total dust) 5 (resp. fract.) 10 (total) 5 (resp. fract.) [vacated 1989 PEL]	NE	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable fraction) PEAK = 2•MAK 15 min, average value, 1-hr interval, 4 per shift Pregnancy Risk Classification: C

NE = Not Established

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

Occupational/Workplace Exposure Limits/Guidelines (continued):

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
Glyceryl Stearate Polyxoyl Stearate Sorbitan Monostearate Exposure limits given are for stearates	11099-07-3 9004-99-3 24634-61-5	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Isopropyl Palmitate	142-91-6	NE	NE	NE	NE	NE	NE	NE	NE
Lactic Acid	50-21-5	NE	NE	NE	NE	NE	NE	NE	NE
Paraffin Exposure limits are for paraffin fume	8002-74-2	2	NE	2 (vacated 1989 PEL)	NE	2	NE	NE	NE
Potassium Sorbate	24634-61-5	NE	NE	NE	NE	NE	NE	NE	NE
Stearyl Alcohol	112-92-5	NE	NE	NE	NE	NE	NE	NE	NE
Water	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

International Occupational Exposure Limits: Currently the following international exposure limits are in place for some components of this product. Limits given may not be the most current and should be checked.

GLYCERIN:
Belgium: TWA = 10 mg/m^3, MAR 2002
Finland: TWA = 20 mg/m^3, NOV 2011
France: VME = 10 mg/m^3, FEB 2006
Germany: MAK = 50 mg/m^3, inhal, 2011
Korea: TWA = 10 mg/m^3 (mist), 2006
Mexico: TWA = 10 mg/m^3 (inhalable), 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (mist), JAN 2002
Peru: TWA = 10 mg/m^3, JUL 2005
Switzerland: MAK-W = 50 mg/m^3, KZG-W = 100 mg/m^3, inhal, JAN 2011
United Kingdom: TWA = 10 mg/m^3, OCT2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

PARAFFIN:
Australia: TWA = 2 mg/m^3 (fume), JUL 2008
Belgium: TWA = 2 mg/m^3 (fume), MAR 2002

PARAFFIN (continued):
Denmark: TWA = 2 mg/m^3 (fume), MAY 2011
Finland: TWA = 1 mg/m^3, fume, NOV 2011
France: VME = 2 mg/m^3 (fume), FEB 2006
Iceland: TWA 2 mg/m^3, NOV 2011
Korea: TWA = 2 mg/m^3, 2006
Mexico: TWA = 2 mg/m^3; STEL = 6 mg/m^3, 2004
The Netherlands: MAC-TGG = 2 mg/m^3, 2003
New Zealand: TWA = 2 mg/m^3, JAN 2002
Norway: TWA= 2 mg/m^3, JAN 1999
Peru: TWA 2 mg/m3, JUL 2005
Switzerland: MAK-W = 2 mg/m^3, resp, JAN 2011
United Kingdom: TWA = 2 mg/m^3; STEL = 6 mg/m^3, OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

STEARYL ALCOHOL:
Austria: MAK 224 mg/m^3 (20 ppm), JAN 2006

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

Respiratory Protection: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Eye Protection: During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

Body Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: Viscous liquid.
COLOR: White to off-white.
ODOR: Slight odor.
ODOR THRESHOLD: Not applicable.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following values are available for the active ingredient, Hydrocortisone:

FORM: Crystalline solid.
COLOR: White to practically white.
MOLECULAR WEIGHT: 362.46
MOLECULAR FORMULA: $C_{21}H_{30}O_5$
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
BOILING POINT @ 760 mmHg: 566.5°C (1051.7°F) [predict.]
MELTING POINT: 217-220°C (422.6-428°F)
VAPOR PRESSURE (air = 1) @ 25°C: 1.35X10-13 mmHg [predict.]
SPECIFIC GRAVITY (water = 1): 1.288 g/cm^3
pH: Not established.
VAPOR DENSITY: Not available.
FLASH POINT: 310.4°C (590.7°F) [predict.]
FLAMMABILITY: Combustible.
SOLUBILITY IN WATER: 30.6 mg/L
OXIDIZING PROPERTIES: Not an oxidizer.

OTHER SOLUBILITIES: Solubilities in various solvents @ 25°C: ethanol: 15.0 mg/mL; methanol: 6.2 mg/mL; acetone: 9.3 mg/mL; chloroform: 1.6 mg/mL; ether: 0.35 mg/mL; propylene glycol: 12.7 mg/mL.

COEFFICIENT WATER/OIL DISTRIBUTION: Log P = 1.762 (predicted)

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: Combustion: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., acrolein, carbon, potassium and nitrogen oxides). **Hydrolysis:** None known.

10. STABILITY and REACTIVITY (Continued)

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Due to the components, this product may be incompatible with strong oxidizing agents, silver nitrate and strong acids.

POSSIBILITY OF HAZARDOUS REACTIONS OR POLYMERIZATION: Will not occur.

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation is unlikely due to viscosity. If aerosols are somehow generated and inhaled, irritation of the nose and upper respiratory system may occur. Symptoms of such exposure may include sneezing, coughing, and nasal congestion. In persons susceptible to corticosteroids, inhalation can cause bronchospasm, with an immediate increase in wheezing. Glaucoma, increased intraocular pressure, and cataracts have been reported following the long-term administration of inhaled corticosteroids.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness and other symptoms described under 'Other Health Effects'. Symptoms of eye contact may include redness, pain, and watering.

Skin Absorption: This product is designed to be absorbed into the 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 of this product is not anticipated to be a significant route of occupational exposure. Ingestion of this product (i.e., through poor hygiene practices) may be harmful or irritate the mouth, throat, and other tissues of the gastrointestinal system. Chronic ingestion can also cause reduction in bone density, immune and adrenal system suppression, and Candida infections. Symptoms of ingestion exposure may include nausea, vomiting, and diarrhea. Non-specified sensitization effects have been reported. Other symptoms as described under 'Other Potential Health Effects' may occur.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

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

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

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

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: 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, skin atrophy, striae, and prickly heat may occur. Symptoms of chronic skin absorption exposure may include reversible hypothalamic-pituitaryadrenal (HPA) axis suppression, abnormal accumulations of facial and trunk fat, fatigue, high blood pressure, osteoporosis, abnormally high level of glucose in the blood, and abnormally high levels of glucose in the urine. Therapeutic use can result in increased susceptibility to infections and may exacerbate systemic fungal infections. Rare instances of anaphylactoid reactions have occurred in persons receiving corticosteroid therapy. Limited evidence of harm to the fetus, based on animal information. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. Other adverse effects reported from therapeutic use described by body system are provided below.

- ***Endocrine System:*** Menstrual irregularities; development of Cushingoid state; suppression of growth in pediatric patients; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness, decreased carbohydrate tolerance; manifestations of latent diabetes requirements for insulin or oral hypoglycemic agents in diabetics.
- ***Eyes:*** Posterior subcapsular cataracts, increased intraocular pressure, glaucoma, bulging eyes.
- ***Fluid and Electrolyte Disturbances:*** Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, high blood pressure.
- ***Gastrointestinal System:*** Peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis.
- ***Metabolic System:*** Negative nitrogen balance due to protein catabolism.
- ***Musculoskeletal System:*** Muscle weakness; steroid myopathy; loss of muscle mass, osteoporosis, vertebral compression fractures, asceptic necrosis of femoral and humeral heads, pathologic fracture of long bones.
- ***Neurological System:*** Convulsions; increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment; vertigo, headache.
- ***Psychological Disorders:*** Psychic derangement may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.
- ***Skin:*** impaired wound healing; thin fragile skin; petechiae and ecchymoses; facial erythema; increased sweating; may suppress reactions to skin tests.

11. TOXICOLOGICAL INFORMATION (Continued)

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

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Ingestion may be harmful.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin) or other effects described under 'Other Potential Health Effects'.

TARGET ORGANS: Acute: Workplace Exposure: Skin. Therapeutic Doses: Fetal harm. Skin. **Chronic:** Workplace Exposure: Skin. Therapeutic Doses: Skin, adrenal system, metabolic system, fetal harm.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue, especially if contact is prolonged.

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.

TOXICITY DATA: The following are toxicity data for the active ingredient. Additional data are available for the excipient components of this product, but are not presented in this SDS. Contact Actavis for more information.

HYDROCORTISONE:

Standard Draize test (Administration onto the skin-Human-Woman) 1%: Moderate
Standard Draize test (Administration onto the skin-Human) 0.5%/2D
TDLo (Oral-Human) 1.43 mg/kg: Cardiac: change in rate; Endocrine: other changes
TDLo (Oral-Human) 0.429 mg/kg: Brain and Coverings: changes in surface EEG; Behavioral: changes in psychophysiological tests
TDLo (Oral-Human-Man) 400 mg/kg/10 days-intermittent: Behavioral-changes in psychophysiological tests
TDLo (Oral-Human-Man) 1.43 mg/kg: Vascular: other changes
TDLo (Oral-Human-Man) 1.4 mg/kg: Behavioral: changes in psychophysiological tests
TDLo (Oral-Human-Man) 0.71 mg/kg: Behavioral: changes in psychophysiological tests; Lungs, Thorax, or Respiration: respiratory stimulation; Endocrine: other changes
TDLo (Oral-Human-Man) 0.29 mg/kg: Endocrine-other changes
TDLo (Intravenous-Human) 0.5 mg/kg: Behavioral: anti-anxiety; Vascular: BP lowering not characterized in autonomic section
TDLo (Intravenous-Human-Woman) 50 mg/kg/5 days-continuous: Behavioral: convulsions or effect on seizure threshold
TDLo (Intravenous-Human-Man) 1 mg/kg: Brain and Coverings: changes in surface EEG; Behavioral: changes in REM sleep (human); Endocrine: other changes
TDLo (Unreported- Human-Man) 5.71 mg/kg/5 days-intermittent: Vascular: BP elevation not characterized in autonomic section
TDLo (Unreported- Human-Man) 1.14 mg/kg: Vascular: BP elevation not characterized in autonomic section
LD_{50} (Oral-Rat) 5000 mg/kg
LD_{50} (Oral-Rat) 600 mg/kg/10 days-intermittent: Brain and Coverings: other degenerative changes
LD_{50} (Oral-Mouse) 5000 mg/kg
LD_{50} (Administration onto the skin-Mouse) 23 mg/kg
LD_{50} (Subcutaneous-Rat) 449 mg/kg: Nutritional and Gross Metabolic: weight loss or decreased weight gain
LD_{50} (Subcutaneous-Mouse) > 500 mg/kg
LD_{50} (Intraperitoneal-Rat) 150 mg/kg: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
LD_{50} (Inhalation-Rat) 31 mg/m3: Liver: other changes; Kidney/Ureter/Bladder: other changes
TDLo (Oral-Rat) 210 mg/kg: female 14 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina
TDLo (Oral-Mouse) 20 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (Oral-Mouse) 140 mg/kg/7 days-intermittent: Endocrine: changes in thymus weight; Nutritional and Gross Metabolic: weight loss or decreased weight gain; Related to Chronic Data: death
TDLo (Oral-Mouse) 10 mg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Administration onto the skin-Mouse) 8.7 mg/kg: Vascular: other changes; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Administration onto the skin-Mouse) 300 mg/kg/10 days-intermittent: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Intraperitoneal-Rat) 50 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (Intraperitoneal-Rat) 150 mg/kg/10 days-intermittent: Kidney/Ureter/Bladder: other changes in urine composition; Biochemical: Metabolism (Intermediary): amino acids (including renal excretion), (Intermediary): other
TDLo (Intraperitoneal-Rat) 80 mg/kg: female 14-15 day(s) after conception: Reproductive: Effects on Newborn: biochemical and metabolic
TDLo (Intraperitoneal-Mouse) 50 mg/kg: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (Intraperitoneal-Mouse) 25 mg/kg: Behavioral: analgesia; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation
TDLo (Intraperitoneal-Mouse) 400 mg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue
TDLo (Subcutaneous-Rat) 50 mg/kg: female 18 day(s) after conception: Reproductive: Effects on Newborn: biochemical and metabolic
TDLo (Subcutaneous-Rat) 330 mg/kg: female 1-22 day(s) after conception: Reproductive: Specific Developmental Abnormalities: endocrine system; Effects on Newborn: growth statistics (e.g.%, reduced weight gain)
TDLo (Subcutaneous-Rat) 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

HYDROCORTISONE (continued):

TDLo (Subcutaneous-Rat) 175 mg/kg/85 days-intermittent: Endocrine: changes in adrenal weight; Nutritional and Gross Metabolic: weight loss or decreased weight gain
TDLo (Subcutaneous-Rat) 200 mg/kg: female 14-15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Subcutaneous-Mouse) 62 mg/kg/11 days-intermittent: Endocrine: other changes
TDLo (Subcutaneous-Mouse) 560 mg/kg/2 weeks-intermittent: Liver: other changes; Blood: agranulocytosis, changes in bone marrow (not otherwise specified)
TDLo (Subcutaneous-Mouse) 100 mg/kg/4 days-intermittent: Liver: changes in liver weight
TDLo (Subcutaneous-Mouse) 400 mg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: craniofacial (including nose and tongue
TDLo (Subcutaneous-Mouse) 156 mg/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 200 mg/kg: female 12 day(s) after conception: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Mouse) 100 mg/kg: female 10-13 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Subcutaneous-Rabbit) 6 mg/kg: female 24-26 day(s) after conception: Reproductive: Effects on Newborn: other neonatal measures or effects, growth statistics (e.g.%, reduced weight gain)
TDLo (Subcutaneous-Guinea Pig) 12 mg/kg: female 16-17 day(s) after conception: Reproductive: Specific Developmental Abnormalities: eye/ear, homeostasis
TDLo (Intramuscular-Rat) 500 mg/kg: female 13 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Intramuscular-Mouse) 400 mg/kg: female 11-14 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Intramuscular-Mouse) 200 mg/kg: female 12 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death
TDLo (Intramuscular-Hamster) 150 mg/kg: female 12 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Intramuscular-Hamster) 333 mg/kg: female 10 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)
TDLo (Intramuscular-Hamster) 400 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: cytological changes (including somatic cell genetic material); Specific Developmental Abnormalities: craniofacial (including nose and tongue)
TDLo (Parenteral-Rat) 50 mg/kg: female 16-18 day(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo
TDLo (Parenteral-Rat) 35 mg/kg: female 7 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina
TDLo (Intraplacental-Mouse) 4 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death; Specific Developmental Abnormalities: other developmental abnormalities
TDLo (Ocular-Rabbit) 2945 µg/kg: female 6-18 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death
TDLo (Unreported-Rat) 100 mg/kg: Liver: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases
DNA adduct (Human Liver) 2 mmol/L
DNA adduct (Human Liver) 2 mmol/L/1 hour
DNA adduct (Human Liver) 2 mmol/plate/1 hour
Unscheduled DNA synthesis (Intraperitoneal-Rat) 20 mg/kg
DNA inhibition (Intraperitoneal-Rat) 100 mg/kg
DNA inhibition (Rat Mammary Gland) 1 mg/L
DNA inhibition (Mouse Cells-Not Otherwise Specified) 100 nmol/L
DNA inhibition (Intraperitoneal-Guinea Pig) 50 mg/kg
DNA inhibition (Guinea Pig Lung) 1 mg/L
DNA inhibition (Bird-Chicken Embryo) 450 pmol/L
Cytogenetic analysis (Intraperitoneal-Mouse) 50 mg/kg
Unscheduled DNA synthesis (Guinea Pig Lung) 1 mg/L
Unscheduled DNA synthesis (Bird-Chicken Embryo) 10 mg/L

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL OF COMPONENTS: The following information is for the active ingredient.

No long-term animal studies have been performed to evaluate carcinogenic potential of corticosteroids.

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

GLYCERYL STEARATE, POLYOXYL STEARATE 40, STEARYL ALCOHOL, as stearate compounds: 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: There are no adequate and well-controlled studies of Hydrocortisone in pregnant women; however, this product may cause fetal harm when administered to a pregnant woman. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category C (refer to Definition of Terms for full category definitions).

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, no ACGIH Biological Exposure Indices (BEIs) have been determined for components.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil; it is expected to be somewhat mobile due to its composition.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bioaccumulation potential.

ECOTOXICITY: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided.

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

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

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

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

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

U.S. EPA WASTE NUMBER: Not applicable.

EUROPEAN WASTE CODES: 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 REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 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 is not classified as Dangerous Goods, by rules of IATA.

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

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

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

14. TRANSPORTATION INFORMATION (Continued)

ENVIRONMENTAL HAZARDS: This product is not environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) no component is listed as a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: No component of this product is 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 under Food and Drug Administration standards; it is not subject to requirements under TSCA.

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

Other U.S. Federal Regulations: Not applicable.

CANADIAN REGULATIONS:

Canadian DSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances LISTS: Isopropanol: Substance with Greatest Potential for Human Exposure Substance on Environment Canada/Health Canada Pilot Project List (CEPA 1999, Section 73).

Canadian WHMIS Classification and Symbol: 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.

Other Canadian Regulations: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

EUROPEAN UNION REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal compound for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

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

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! MAY BE HARMFUL IF SWALLOWED. PROLONGED SKIN CONTACT MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE EYE IRRITATION. MAY CAUSE ALLERGIC SKIN REACTION. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY. COMBUSTIBLE-MAY IGNITE IF HIGHLY HEATED FOR A PROLONGED PERIOD. Do not taste or swallow. Avoid non-therapeutic contact with skin or contact with clothing. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, call a physician immediately. Do NOT induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

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

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Hydrocortisone: The following is a Self-Classification.

Classification: Reproductive Toxicity Category 2, Skin Irritation Category 2, Acute Oral Toxicity Category 5, Acute Inhalation Toxicity Category 5, Acute Dermal Category 5, Skin Sensitization Category 1B

Hazard Statements: H361d: Suspected of damaging the unborn child. H315: Causes skin irritation. H303 + H313 + H333: May be harmful if swallowed, in contact with skin or if inhaled. H317: May cause an allergic skin reaction.

Glycerin, Paraffin: This is a self-classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if ingested.

Lactic Acid: This is a self-classification.

Classification: Acute Oral Toxicity Category 5, Acute Dermal Toxicity Category 5, Skin Irritation Category 2, Eye Damage Category 1B

Hazard Statements: H303 + H313: May be harmful if swallowed or in contact with skin. H315: Causes skin irritation. H318: Causes serious eye damage.

Stearyl Alcohol: This is a self-classification.

Classification: Skin Irritation Cat. 2, Eye Irritation Category 2A, Acute Oral Toxicity Category 5

Hazard Statements: H315: Causes skin irritation. H319: Causes serious eye irritation. H303: May be harmful if swallowed.

All Other Components: An official classification for these substances has not been published in the CLP 1272: 2008 and a self-classification is not applicable.

16. OTHER INFORMATION (Continued)

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.
REVISION DETAILS: New.

This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this compound. To the best of Actavis, Inc. knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific compound. If this compound is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

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