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: Clobetasol Propionate Cream, USP 0.05%

DESCRIPTION: Topical Clobetasol Propionate Cream
CHEMICAL NAME: Active Ingredient: 21-chloro-9-fluoro-11β, 17-dihydroxy-16β -methylpregna-1,4-diene-3,20-dione 17-propionate
CHEMICAL FAMILY: Synthetic Fluorinated Corticosteroid
HOW SUPPLIED: 0.05% Clobetasol Propionate Cream
OTHER DESIGNATIONS: NDC: 00472040015: 15 gm; NDC: 00472040030: 30 gm; NDC: 00472040045: 45 gm
NDC: 00472040060: 60 gm
FORMULA: Active Ingredient: $C_{25}H_{32}ClFO_5$
RELEVANT USE of the SUBSTANCE: Human Pharmaceuticals
USES ADVISED AGAINST: Non-Pharmaceutical Use

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], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This compound has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: November 11, 2014 **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.

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

EMERGENCY OVERVIEW:

Product Description: This product is a white, opaque cream with a mild odor.

Health Hazards: This product may cause irritation by all routes of exposure. In therapeutic use, the most common adverse effect reported has been application site burning and itching. Due to the Chlorocresol component, skin contact may cause skin sensitization and allergic reaction in susceptible individuals. As a corticosteroid, allergic contact dermatitis can occur, as determined by a failure to heal. Skin infections including fungal infections can occur. Prolonged or chronic use can lead to increased susceptibility to infections, including the flu, nasopharyngitis, strep, and upper respiratory tract infections. Systemic skin absorption of topical corticosteroids has produced hypothalamic-pituitary-adrenal (HPA) axis suppression manifestations of Cushing's syndrome, high blood sugar, and glucose in the urine. Limited evidence of harm to fetus during pregnancy, based on animal data. Breastfeeding during therapeutic use may cause harm to breastfed babies. 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 may ignite if exposed to direct flame or if highly heated for a prolonged period, causing water to evaporate. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sodium and nitrogen oxides, phosgene and hydrogen chloride).

Environmental Hazards: The active ingredient may cause long-term harm to aquatic organisms and the Chlorocresol component is acutely toxic to aquatic organisms. 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 EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENT:				
Clobetasol Propionate	25122-46-7	246-634-3	0.05%	SELF-CLASSIFICATION EU 67/548 Classification: Reproductive Toxicity Cat. 3, Harmful, Dangerous for the Environment Risk Phrases: R62, R63, R64, R48/20/21, R53 Hazard Symbol: Xn, N EU/GHS 1272/2008 Classification: Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 5, Adverse Effects on or Via Lactation, STOT (Skin/Inhalation-Adrenal Gland, Immune System) RE Cat. 2 Hazard Statement Codes: H303, H361fd, H362, H373, H412 Hazard Symbol/Pictogram: GHS08
EXCIPIENTS:				
Cetostearyl Alcohol	67762-27-0	267-008-6	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Chlorocresol	59-50-7	200-431-6	Proprietary	EU 67/548 Classification: Harmful, Irritant, Dangerous for the Environment Risk Phrases: R21/22, R41, R43, R50 Hazard Symbol: Xn/Xi, N EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Acute Dermal Toxicity Cat. 4, Eye Damage Cat. 1, Skin Sensitization Cat. 1, Aquatic Acute Toxicity Cat. 1 Hazard Statement Codes: H320 + H312, H318, H317, H400 Hazard Symbol/Pictogram: GHS05, GHS07, GHS08, GHS09
Citric Acid	77-92-9	201-069-1	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Irritant Risk Phrases: R36 Hazard Symbol: Xi EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Eye Irritation Cat. 2A Hazard Statement Codes: H303, H319 Hazard Symbol/Pictogram: GHS07
Glyceryl Monostearate	31566-31-1	250-705-4	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Glyceryl Stearate	111-60-4	203-886-9	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Polyethylene Glycol 100 Stearate	9004-99-3	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Propylene Glycol	57-55-6	200-338-0	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sodium Citrate	68-04-2	200-675-3	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
White Wax	8001-75-0	232-290-1	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Purified Water	7732-18-5	231-791-2	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not 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 aerosols 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).

4. FIRST-AID MEASURES (Continued)

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, preexisting skin conditions, hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, and glucosuria, may be aggravated by exposure to this product. Workplace exposure may cause aggravation.

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

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not determined.

AUTOIGNITION TEMPERATURE: Not determined.

FLAMMABLE LIMITS (in air by volume, %): The following values are for

FIRE EXTINGUISHING MEDIA: In the event of a fire, use suppression methods for surrounding materials, including water spray (for cooling), dry extinguishing media, carbon dioxide, foam.

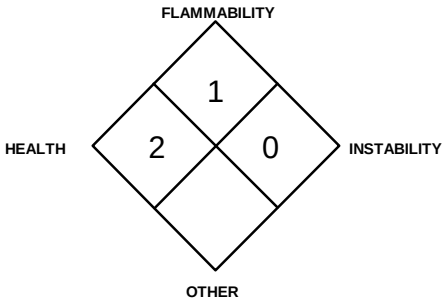
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL FIRE AND EXPLOSION HAZARDS: This product may be combustible and may ignite if exposed to direct flame or if highly heated for a prolonged period, causing water to evaporate. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, sodium and nitrogen oxides, phosgene and hydrogen chloride).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



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

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

7. HANDLING and USE (Continued)

PRECAUTIONS FOR SAFE HANDLING (continued): Keep container tightly closed when not in use. 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.

WORK PRACTICES AND HYGIENE PRACTICES: 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 compound, and during patient administration.

STORAGE AND HANDLING PRACTICES: Store containers in a cool, dry location, away from direct sunlight, sources of intense heat, 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). 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.

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.

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:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA	STEL	TWA	STEL	TWA	STEL	IDLH	
		ppm	ppm	ppm	ppm	ppm	ppm	ppm	ppm
Clobetasol Propionate	25122-46-7	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	67762-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Chlorocresol	59-50-7	NE	NE	NE	NE	NE	NE	NE	DFG MAK: Danger of Sensitization of the Skin
Citric Acid	77-92-9	NE	NE	NE	NE	NE	NE	NE	NE
Glyceryl Monostearate	31566-31-1	NE	NE	NE	NE	NE	NE	NE	NE
Glyceryl Stearate	111-60-4	NE	NE	NE	NE	NE	NE	NE	NE
Polyethylene Glycol Monostearate	9004-99-3	NE	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10 mg/m^3
Sodium Citrate	68-04-2	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.

CHLOROCRESOL:
The Netherlands: MAC-TGG = 3 mg/m^3, 2003
Sweden: TWA = 3 mg/m^3; STEL = 6 mg/m^3, Sen, JUN 2005

CITRIC ACID:
Russia: STEL = 1 mg/m^3, JUN 2003

PROPYLENE GLYCOL:
Australia: TWA = 10 mg/m^3 (particulates), JUL 2008

PROPYLENE GLYCOL (continued):
Australia: TWA = 150 ppm (474 mg/m^3) (total), JUL 2008
New Zealand: TWA = 10 mg/m^3 (particulates only), JAN 2002
New Zealand: TWA = 150 ppm (474 mg/m^3) (vapor and particulates), JAN 2002
Russia: STEL = 7 mg/m^3, JUN 2003
United Kingdom: TWA = 10 mg/m^3 (particulate), OCT 2007
United Kingdom: TWA = 150 ppm (474 mg/m^3) (total vapor and particulate), OCT 2007

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: No eye protection is normally needed during medical administration of this product. During operations in which aerosols of the product may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. 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: Liquid.
COLOR: Opaque, white.
MOLECULAR WEIGHT: Mixture
MOLECULAR FORMULA: Mixture
ODOR: Mild.
RELATIVE VAPOR DENSITY (air = 1): Not available.
ODOR THRESHOLD: Not available.
VISCOSITY: Not available.
EVAPORATION RATE (nBuAc = 1): Not available.
pH: Not available.
FLAMMABILITY: May be combustible.
FLASH POINT: Not tested.
BOILING POINT: Not available.
FREEZING/MELTING POINT: Not available.
EXPLOSIVE PROPERTIES: Not explosive.
OXIDIZING PROPERTIES: Not an oxidizer.
SOLUBILITY IN WATER: Insoluble.
OTHER SOLUBILITY: Not available.
VAPOR PRESSURE (air = 1): Not available.
SPECIFIC GRAVITY (water = 1): Not available.
HOW TO DETECT THIS SUBSTANCE (identification properties): There are no good identification properties in event of an accidental spill.

The following values are available for the active ingredient, Clobetasol Propionate:

FORM: Crystalline solid.
COLOR: White.
MOLECULAR WEIGHT: 466.97
MOLECULAR FORMULA: $C_{25}H_{32}ClFO_5$
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
BOILING POINT @ 760 mmHg: 569.0±50.0°C (1056.2±122°F) [predict.]
MELTING POINT: 199-200°C (390.2-392°F)
VAPOR PRESSURE (air = 1) @ 25°C: 0.0±3.5 mmHg [predict.]
SPECIFIC GRAVITY (water = 1): 1.3±0.1 g/cm^3 [predict.]
EVAPORATION RATE (nBuAc = 1): Not available.
SOLUBILITY IN WATER: Practically insoluble: < 1 mg/L
FLASH POINT: 297.9±30.1°C (568.9±86.2°F) [predict.]
OTHER SOLUBILITIES: Not available.
COEFFICIENT WATER/OIL DISTRIBUTION: Log P: 3.98±0.61 [predict.]

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product has no known reactivity and is stable when properly stored (see Section 7, Handling and Storage).

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

MATERIALS WITH WHICH PRODUCT IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility.

POSSIBILITY OF HAZARDOUS REACTIONS/POLYMERIZATION: Polymerization will not occur.

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE 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: Although unlikely due to viscosity, if aerosols inhaled, coughing and temporary bronchial irritation may occur. Symptoms are generally alleviated upon breathing fresh air. Inhalation may cause adverse effects as described under 'Other Health Effects'.

Contact with Skin or Eyes: Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged skin contact may cause dermatitis (dry, red, cracked skin), thinning of skin and suppression of adrenal cortex (decreased ability to respond to stress) and increased susceptibility to bacterial and fungal infections. Contact of this product with the eyes may cause moderate to severe irritation, redness, and tearing.

Skin Absorption: This product is designed to be absorbed via intact skin. Prolonged or chronic skin exposure can cause adverse effects as described under 'Other Health Effects'.

Ingestion: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may cause adverse symptoms as described for "Other Potential Health Effects".

Injection: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for "Other Potential Health Effects".

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, the most common adverse effect reported has been application site burning and itching. Other effects reported have included itching, skin atrophy, and cracking and fissuring of the skin, burning sensation, irritation, cracking, erythema, inflammation and/or infection in the hair follicles, numbness of fingers, and spider veins. As a corticosteroid, allergic contact dermatitis can occur, as determined by a failure to heal.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued): Skin infections including fungal infections can occur. Prolonged or chronic use can lead to increased susceptibility to infections, including the flu, nasopharyngitis, strep, and upper respiratory tract infections. Systemic skin absorption of topical corticosteroids has produced hypothalamic-pituitary-adrenal (HPA) axis suppression manifestations of Cushing's syndrome, high blood sugar, and glucose in the urine. Limited evidence of harm to fetus during pregnancy, based on animal data. Breastfeeding during therapeutic use may cause harm to breastfed babies. In therapeutic use the following additional adverse effects described by body system have included:

- ***Reproductive System:*** Possible harm to fetus, possible harm to breastfed babies.
- ***Skin:*** Infection in the hair follicles, eruptive acne, hypopigmentation, small round bumps around mouth, allergic contact dermatitis, secondary infection, stripping of skin and sweat rash.

IRRITANCY OF PRODUCT: This product may mildly to moderately irritate contaminated tissue if contact is prolonged.

SENSITIZATION OF PRODUCT: In therapeutic use, this product has been reported to cause allergic contact dermatitis. The Chlorocresol component can cause skin sensitization and allergic reaction in susceptible individuals.

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

Acute: This product may cause irritation by all routes of exposure. May be harmful if ingested.

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

TARGET ORGANS: Acute: Industrial Exposure: Skin. Therapeutic Doses: Skin. **Chronic:** Industrial Exposure: Skin, immune and adrenal systems. Therapeutic Doses: Adrenal and immune systems, skin.

TOXICITY DATA: This SDS presents human toxicity data and LD_{50} Oral-Rat and LD_{50} Oral-Mouse currently available for the active component. Additional data are available for the active component and data are available for other components of this product, but are not presented in this SDS. Contact Watson Pharmaceuticals for more information.

CLOBETASOL PROPIONATE:

Standard Draize Test (Skin-Human) 1%: Moderate
Standard Draize Test (Skin-Human) 0.1%/2 days
LD_{50} (Oral-Rat) > 3 gm/kg
LD_{50} (Oral-Mouse) > 3 gm/kg
LD_{50} (Intraperitoneal-Rat) 351 mg/kg
LD_{50} (Intraperitoneal-Mouse) 118 mg/kg
LD_{50} (Subcutaneous-Rat) 366 mg/kg
LD_{50} (Subcutaneous-Mouse) 81,700 µg/kg
TDLo (Skin-Rat) 17,500 µg/kg/5 weeks-intermittent: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol), changes in leukocyte (WBC) count; Nutritional and Gross Metabolic: weight loss or decreased weight gain

CLOBETASOL PROPIONATE (continued):

TDLo (Skin-Rat) 3750 µg/kg/30 days-intermittent: Blood: changes in bone marrow (not otherwise specified); Nutritional and Gross Metabolic: weight loss or decreased weight gain; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases
TDLo (Subcutaneous-Rat) 2275 mg/kg/13 weeks-intermittent: Behavioral: somnolence (general depressed activity); Skin and Appendages: hair; Nutritional and Gross Metabolic: weight loss or decreased weight gain
TDLo (Subcutaneous-Rat) 2600 µg/kg: female 17-22 day(s) after conception lactating female 21 day(s) post-birth: Reproductive: Maternal Effects: parturition; Effects on Newborn: live birth index (measured after birth), other neonatal measures or effects

CARCINOGENIC POTENTIAL OF COMPONENTS: Long-term animal studies have not been performed to evaluate the carcinogenic potential of Clobetasol Propionate.

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 this product 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 (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks).

Mutagenicity: Clobetasol Propionate was negative in the in vitro mammalian chromosomal aberration test and in the in vivo mammalian erythrocyte micronucleus test.

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 to laboratory animals. Clobetasol propionate is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. The effect of Clobetasol Propionate on pregnancy outcome and development of offspring was studied in the rat. Clobetasol propionate was administered subcutaneously to female rats twice daily (0, 12.5, 25, and 50 µg/kg/day) from day 7 of presumed gestation through day 25 of lactation or day 24 presumed gestation for those rats that did not deliver a litter. The maternal NOEL for Clobetasol Propionate was less than 12.5 µg/kg/day due to reduced body weight gain and feed consumption during the gestation period. The reproductive NOEL in the dams was 25 µg/kg/day (ratio of animal dose to proposed human dose of 0.07 on a mg/m^2/day basis) based on prolonged delivery at a higher dose level. The no-observed-adverse-effect-level (NOAEL) for viability and growth in the offspring was 12.5 µg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m^2/day basis) based on incidence of stillbirths, reductions in pup body weights on days 1 and 7 of lactation, increased pup mortality, increases in the incidence of umbilical hernia, and increases in the incidence of pups with cysts on the kidney at higher dose levels during the pre-weaning period. The weights of the epididymides and testes were significantly reduced at higher dosages. Despite these changes, there were no effects on the mating and fertility of the offspring.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Reproductive Toxicity: The effect of subcutaneously administered Clobetasol Propionate on fertility and general reproductive toxicity was studied in rats at doses of 0, 12.5, 25, and 50 µg/kg/day. Males were treated beginning 70 days before mating and females beginning 15 days before mating through day 7 of gestation. A dosage level of less than 12.5 µg/kg/day Clobetasol Propionate was considered to be the no-observed-effect-level (NOEL) for paternal and maternal general toxicity based on decreased weight gain and for male reproductive toxicity based on increased weights of the seminal vesicles with fluid. The female reproductive NOEL was 12.5 µg/kg/day (ratio of animal dose to proposed human dose of 0.03 on a mg/m2/day basis) based on reduction in the numbers of estrous cycles during the pre-cohabitation period and an increase in the number of nonviable embryos at higher doses. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil. The following information is available for the Chlorocresol component.

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

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

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

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential. The following information is available for the Chlorocresol component.

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

ECOTOXICITY: 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. No specific data is available for this product. The active ingredient may cause long-term harm to aquatic organisms. The following aquatic toxicity data are available for the active ingredient and the Chlorocresol component. Only select data are provided in this SDS; contact Actavis, Inc. for additional information.

CLOBETASOL PROPIONATE:

EC_{50} (*Oncorhynchus mykiss* rainbow trout) 96 hours = > 0.75 mg/L
EC_{50} (*Daphnia magna* Water flea) 48 hours = > 1.4 mg/L
IC_{50} (Selenastrum algae) 72 hours = > 4.2 mg/L
IC_{50} (Other Microorganisms) 3 hours = > 100 mg/L

CHLOROCRESOL:

EC_{50} (*Chlorella pyrenoidosa* Green Algae) 72 hours = 15,000 µg/L
EC_{50} (*Daphnia magna* Water flea); 24 hours = 2780-4400 µg/L
LC_{50} (*Pimephales promelas* fathead minnow) 30 day old; 96 hours = 4.05 mg/L
LC_{50} (*Daphnids*) 0.17 mg/L

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

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

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

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

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.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified under United Nations Economic Commission for Europe to be dangerous goods.

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

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

15. REGULATORY INFORMATION

ADDITIONAL UNITED STATES REGULATIONS:

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

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

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

U.S. TSCA Inventory Status: This product is regulated 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/NDSL 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: Not applicable.

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.

EUROPEAN REGULATIONS:

Safety, Health, And Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal product 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! CHRONIC SKIN CONTACT OR INHALATION MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE ALERGIC CONTACT DERMITITIS. MAY CAUSE IRRITATION BY ALL ROUTES OF EXPOSURE. MAY CAUSE HARM TO FETUS DURING PREGNANCY. BREAST-FEEDING DURING THERAPEUTIC USE MAY CAUSE HARM TO BREAST-FED BABIES. Keep away from heat, sparks, and flame. Avoid contact with skin, eyes, and clothing. Avoid breathing vapors. 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 skin or 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, do NOT induce vomiting. If vomiting occurs, have person lean forward. Call physician or poison control center immediately. 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 residue in appropriate container and seal. Dispose of according to applicable regulations. Consult Material 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.

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

16. OTHER INFORMATION (Continued)

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Clobetasol Propionate: This is a self-classification.

Classification: Reproductive Toxicity Category 2, Acute Oral Toxicity Category 5, Adverse Effects on or Via Lactation, Specific Target Organ Toxicity (Skin/Inhalation-Adrenal Gland, Immune System) Repeated Exposure Category 2

Hazard Statements: H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child. H303: May be harmful if swallowed. H362: May cause harm to breast-fed children. H373: May cause damage to adrenal and immune systems, through prolonged or repeated exposure by skin contact or inhalation. H412: Harmful to aquatic life with long-lasting effects.

Chlorocresol: This is a published classification.

Classification: Acute Oral Toxicity Category 4, Acute Dermal Toxicity Category 4, Eye Damage Category 1, Skin Sensitization Category 1, Aquatic Acute Toxicity Category 1

Hazard Statements: H302 + H312: Harmful if swallowed or in contact with skin. H318: Causes serious eye damage. H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life.

Citric Acid: This is a self-classification.

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

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

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.

67/548/EEC:

Clobetasol Propionate: This is a self-classification.

Classification: Reproductive Toxicity Category 3, Harmful, Dangerous for the Environment

Risk Phrases: R62: Possible risk of impaired fertility. R63: Possible risk of harm to the unborn child. R64: May cause harm to breast-fed babies. R48/20/21: Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin. R53: May cause long-term adverse effects in the aquatic environment.

Chlorocresol: This is a published classification.

Classification: Harmful, Irritant, Dangerous to the Environment

Hazard Statements: R21/22: Harmful in contact with skin and if swallowed. R41: Risk of serious damage to eyes. R43: May cause sensitisation by skin contact. R50: Very toxic to aquatic organisms.

Citric Acid: This is a self-classification.

Classification: Irritant

Hazard Statements: R36: Irritating to eyes.

All Other Components: An official classification for these substances has not been published in Commission Directives and a self-classification is not applicable.

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.

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