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: 1753 DOCOSANOL CREAM 10%

DESCRIPTION: Docosanol Topical Cream
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: Docosan-1-ol
CHEMICAL FAMILY: For Active Ingredient: Aliphatic Fatty Alcohol
FORMULA: For Active Ingredient: $C_{22}H_{46}O$
HOW SUPPLIED: 10% Docosanol Cream

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**Actavis, Inc.**
U.S. ADDRESS:	400 Interpace Parkway, Morris Corporate Center III Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL SDS INFORMATION:	1-800-272-5525
RESPONSIBLE PARTY EUROPE:	
EUROPEAN ADDRESS:	
EUROPEAN BUSINESS PHONE:	
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: +1-703-527-3887 (24 hours) Outside North America
Email:	SDS@Actavis.com

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: October 9, 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 lotion.

Health Hazards: May be harmful if ingested. Eye contact can cause moderate irritation. Although unlikely due to form, inhalation may cause respiratory irritation. In therapeutic use, the most common adverse effects reported include headache (incidence similar to placebo), application site reaction (e.g., burning, stinging) (incidence similar to placebo), and herpes simplex outside the treatment area (incidence similar to placebo). Other application site effects reported have included acne, burning, dryness, itching, rash, redness, soreness, swelling. Refer to Section 11 (Toxicological Information) for more information on potential health effects 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 and water evaporates. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).

Environmental Hazards: This product has not been tested for environmental effect. 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				
Docosanol Docosan-1-ol	661-19-8	211-546-6	10.0%	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Aquatic Chronic Toxicity Cat. 4 Hazard Codes: H413
EXCIPIENTS:				
Light Mineral Oil	8042-47-5	232-455-8	5.0-10.0%	GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Aspiration Hazard Cat. 1 Hazard Statement Codes: H304

See Section 16 for full classification information.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS GHS Under U.S. OSHA & EU Classification (1272/2008 EC) Hazard Statement Codes
EXCIPIENTS (continued):				
Sucrose Stearate	37318-31-3	253-459-6	4.0-6.0%	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Sucrose Monostearate	25168-73-4	246-705-9		GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Propylene Glycol	57-55-6	200-338-0	3.0-6.0%	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Benzyl Alcohol	100-51-6	202-859-8	1.0-3.0%	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 4, Acute Inhalation Toxicity Cat. 4 Hazard Statement Codes: H302 + H332
Purified Water	7732-18-5	231-791-2	Balance	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 may be aggravated by exposure to this product. Persons who may have hypersensitivity reactions to components 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. There is no specific antidote for this drug; therefore, management of the patient should consist of symptomatic and supportive therapy.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

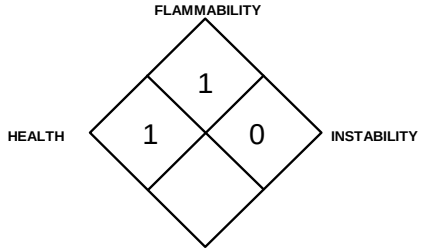
FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not determined.

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

UNSUITABLE 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., carbon and nitrogen oxides).

NFPA RATING



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

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

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

6. ACCIDENTAL RELEASE MEASURES (Continued)

PERSONAL PRECAUTIONS (continued): 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 product, 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 the product, 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.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store at 20-25°C (68-77°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 human pharmaceutical. Follow all industry standards for use of this product.

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 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
Docosanol	661-19-8	NE	NE	NE	NE	NE	NE	NE	Actavis WEL: 500 $\mu g/m^3$

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
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA: 10 ppm
Light Mineral Oil Exposure limits are for mineral oils, pure, highly or severely refined	8042-47-5	5 (inhal. fract.)	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3, TLV-A4
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Sucrose Stearates Exposure limits given are for stearates	25168-73-4 37318-31-3	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
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.

BENZYL ALCOHOL:
Finland: TWA = 10 ppm (45 mg/m^3), NOV 2011
Russia: STEL = 5 mg/m^3, Skin, JUN 2003

LIGHT MINERAL OIL:
Russia: STEL = 5 mg/m^3, Skin, JUN 2003

PROPYLENE GLYCOL:
Australia: TWA = 10 mg/m^3 (particulates), JUL 2008
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: 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: Creamy, viscous liquid.
COLOR: White to off-white.
MOLECULAR WEIGHT: Mixture.
MOLECULAR FORMULA: Mixture.
ODOR: Faint odor.
ODOR THRESHOLD: Not applicable.

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance of this product may act as a distinguishing characteristic.

The following values are for the Docosanol active ingredient.

FORM: Crystalline solid.
COLOR: White to light yellow.
MOLECULAR WEIGHT: 326.6
MOLECULAR FORMULA: $C_{22}H_{46}O$
ODOR: Not available.
ODOR THRESHOLD: Not available.
BOILING POINT @ 22 mmHg: 180°C (356°F)
MELTING POINT: 72.5°C (162.5°F)
VAPOR PRESSURE (air = 1) @ 20°C: 0 < 1 hPa
SPECIFIC GRAVITY (water = 1): 1.452 g/cm^3 [predict.]
EVAPORATION RATE (nBuAc = 1): Not applicable.
FLASH POINT: 142.5±5.2°C (288.5±41.4°F) [predict.]
SURFACE TENSION: 31.8±3.0 dyne/cm [predict.]
AUTOIGNITION TEMPERATURE: Not available.
pH: Not available.
SOLUBILITY IN WATER @ 25°C: Insoluble (0.0027 mg/L).

OTHER SOLUBILITIES: Slightly soluble in ether; very soluble in ethanol, methanol, petroleum ether; soluble in chloroform.
COEFFICIENT WATER/OIL DISTRIBUTION: Log Kow = 9.68 (est.); Log P: 10.44 [predict.]

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., carbon and nitrogen oxides). **Hydrolysis:** None known.

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 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: Although unlikely due to the form of the product, if vapors, mists, or sprays are inhaled, bronchial irritation may occur. No other effect is known by the route of exposure.

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). Contact of this product with the eyes may cause moderate irritation, redness, and tearing.

Skin Absorption: As this product is designed to be absorbed via skin, no significant adverse effect is expected under normal situations of use and handling.

Ingestion: Ingestion is not a significant route of workplace exposure. Ingestion caused by poor hygiene practices may cause adverse symptoms, including, nausea, gastrointestinal irritation and other symptoms described under 'Other Potential Health Effects.

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)	1
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 effects reported include headache (incidence similar to placebo), application site reaction (e.g., burning, stinging) (incidence similar to placebo), and herpes simplex outside the treatment area (incidence similar to placebo). Other application site effects reported have included acne, burning, dryness, itching, rash, redness, soreness, swelling. Exposure (no route reported) to large quantity has been reported to cause abdominal pain, increased serum lipase, nausea, upset stomach, dizziness, and excess bilirubin in blood. It is not known if these effects may also be experienced from occupational exposure.

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. Eye contact will cause irritation.

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: Skin. **Chronic:** Workplace Exposure: Skin. Therapeutic Doses: Skin.

IRRITANCY OF PRODUCT: This product may cause irritation in contact with the eyes or if inhaled.

SENSITIZATION OF PRODUCT: In therapeutic use, some rare reports of hypersensitivity reactions have included difficulty breathing, confusion, facial swelling, fainting, dizziness, hives and chest pain.

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.

DOCOSANOL:

LD_{50} (Intraperitoneal-Mouse) > 800 mg/kg
LD_{50} (Subcutaneous-Mouse) >800 mg/kg
LD_{50} (Intravenous-Mouse) >800 mg/kg

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

Carcinogenicity tests were not conducted with Docosanol.

The excipient components are listed as follows:

Light Mineral Oil: ACGIH TLV-A4 (Not Classifiable as to Carcinogenicity in Humans); IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Docosanol in pregnant women; however, when administered therapeutically, this product is not expected to cause fetal harm when administered to a pregnant woman. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category B (Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.).

Mutagenicity: Docosanol did not increase the number of revertants per plate compared to controls in the *S. typhimurium* assay, with or without metabolic activation. No significant increases in the number of mutant colonies or in structural chromosome aberrations were observed in Chinese hamster V79 cells. In addition, Docosanol did not increase the frequency of bone marrow polychromatic erythrocyte (PCE) micronuclei in mice *in vivo*.

Embryotoxicity/Teratogenicity: Developmental or Reproductive Toxicity/ ... Docosanol demonstrated no effects on the fertility or reproduction of rats dosed up to 1000 mg/kg body weight. Similarly, Docosanol had no reproductive effects on rabbits treated with doses up to 2000 mg/kg body weight. The observation of pale feces was the only compound-related effect reported, limited to rabbits treated with 2000 mg Docosanol/kg body weight.

Reproductive Toxicity: In animal testing, involving rats, Docosanol had no effects on weight and histological appearance of the prostate in intact rats but increase the RNA/DNA quotient in the ventral prostate. Plasma concentration of luteinizing hormone and testosterone were reduced. In orchiectomized animals it increased the weight of prostate and adrenals.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Reproductive Toxicity (continued): In adrenalectomized, orchiectomized animals, Docosanol did not increase prostatic weight but on the contrary caused further weight reduction. Docosanol had a thymolytic effect in intact rats but not in adrenalectomized rats in which the thymus weight was increased. Docosanol increased adrenal steroid secretion. No adverse effects on fertility were seen when rats and rabbits were dosed with either 1000 mg/kg/day or 2000 mg/kg/day, (2500 to 5000 times the expected human dose, respectively). Furthermore, rabbits did not exhibit any adverse effects on fertility following vaginal administration of Docosanol. It is not known whether Docosanol is distributed into breast milk; however, problems in humans have not been documented. Because there is potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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. The following information is available for the active ingredient.

DOCOSANOL:

Biodegradability aerobic - Exposure time 28 days, Result: 37 %: Not readily biodegradable.(OECD Test Guideline 301B)

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. No aquatic toxicity data are available for the active ingredient. Contact Actavis for more information.

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.

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 is on the California Proposition 65 lists.

Other U.S. Federal Regulations: Not applicable.

ADDITIONAL 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: 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.

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

ADDITIONAL 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): CAUTION! MAY CAUSE EYE IRRITATION. MAY BE HARMFUL IF INGESTED. PROLONGED SKIN CONTACT MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE CHRONIC EFFECTS TO AQUATIC ENIVRONMENT. COMBUSTIBLE LIQUID WHICH MAY BE IGNITED IF HIGHLY HEATED FOR A PROLONGED PERIOD. 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 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

Docosanol: This is a self-classification.

Classification: Aquatic Chronic Toxicity Category 4

Hazard Statements: H413: May cause long-lasting harmful effects to aquatic life.

Benzyl Alcohol: This is a self-classification.

Classification: Acute Oral Toxicity Category 4, Acute Inhalation Toxicity Category 4

Hazard Statements: H302 + H332: Harmful if swallowed or in inhaled.

Mineral Oil: This is a self-classification.

Classification: Aspiration Hazard Category 1

Hazard Statements: H304: May be fatal if swallowed and enters airways.

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

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.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

DATE OF PRINTING: October 13, 2015