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: ESTRACE® (Estradiol Vaginal Cream, USP, 0.01%)

DESCRIPTION: Estradiol Cream
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: Estra-1,3,5,(10)-triene-3, 17β-diol
CHEMICAL FAMILY: For Active Ingredient: Estrogen
HOW SUPPLIED: 0.01% Estradiol Cream
OTHER DESIGNATIONS: 0.1 mg in 1 g Cream in Tubes with Applicator: NDC:0430-3754-14; NDC:0430-3754-95
FORMULA: For Active Ingredient: $C_{18}H_{24}O_2$

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 30, 2013 **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 to off-white cream supplied in tubes with an applicator.

Health Hazards: The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin. In therapeutic use, the most common adverse effects reported include headache, breast pain, irregular vaginal bleeding or spotting, stomach/abdominal cramps, bloating, nausea and vomiting, hair loss. May be absorbed through the skin. Chronic exposure may cause temporary impairment of fertility in both genders; interference with egg and sperm production. In men, exposure to female hormones has been associated with testicular atrophy, increased risk of prostate cancer, gynecomastia, loss of libido and potency. Can cause fetal harm in pregnancy, as an estrogen. Long-term therapeutic use can cause adverse effects on cardiovascular system with a greater risk for cigarette smokers. Limited evidence of carcinogenic effect; prolonged therapy poses a greater risk of cancer in post-menopausal women. 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. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sodium 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 EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Estradiol estra-1,3,5,(10)-triene-3, 17β-diol	50-28-2	200-023-8	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Carcinogenic Cat. 3, Reproductive Toxicity Cat. 2, Reproductive Toxicity Cat. 3, Harmful Risk Phrase Codes: R40, R61, R62, R33, R64 Hazard Symbols: T, Xn GHS and EU 1272/2008 Classification: Carcinogenic Cat. 2, Reproductive Toxicity Cat. 1B, STOT (Cardiovascular System) RE Cat. 2, Effects on or Via Lactation Hazard Codes: H351, H360Df, H373, H362 Hazard Symbol/Pictogram: GHS08
Edetate Sodium	6381-92-6	For Anhydrous: 200-449-4	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Hypromellose	9004-65-3	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Methyl Paraben	99-76-3	202-785-7	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
Mono and di Glycerides	67701-32-0	226-951-0	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sodium Lauryl Sulfate	151-21-3	205-788-1	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrases: R22, R36 Hazard Symbols: Xn GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Eye Irritation Cat. 2A Hazard Codes: H302, H319 Hazard Symbol/Pictogram: GHS07
Stearyl Alcohol	112-92-5	204-017-6	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Tertiary Butylhydroquinone	1948-33-0	217-752-2	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Germ Cell Mutagen Cat. 3, Harmful Risk Phrase Codes: R22, R68 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Germ Cell Mutagen Cat. 2, Acute Oral Toxicity Cat. 4 Hazard Codes: H341, H302 Hazard Symbol/Pictogram: GHS07, GHS08
Purified Water	7732-18-5	231-791-2	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
White Ceresin Wax	8001-75-0	232-290-1	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 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, preexisting endometriosis, asthma, diabetes mellitus, epilepsy, migraine or porphyria (inherited neurological or skin conditions), systemic lupus erythematosus, non-cancerous liver tumors, and liver, renal or cardiac dysfunction (with a greater risk for cigarette smokers) may be aggravated by exposure to this product. Workplace exposure may cause aggravation.

4. FIRST-AID MEASURES (Continued)

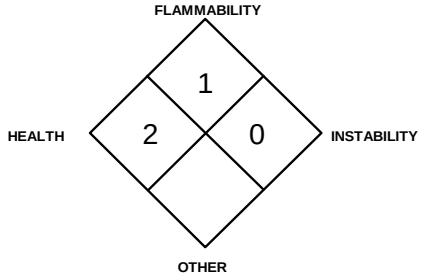
INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing. If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used.

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., carbon and nitrogen oxides).

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

NFPA RATING



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

SPECIAL 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).

7. HANDLING and USE (Continued)

PRECAUTIONS FOR SAFE HANDLING (continued): 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 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:

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
Estradiol	50-28-2	NE	NE	NE	NE	NE	NE	NE	Actavis WEL: 0.015 µg/m^3
Edetate Sodium	6381-92-6	NE	NE	NE	NE	NE	NE	NE	NE
Hypromellose Exposure limits are for cellulose	9004-65-3	10	NE	15 (total dust), 5 (respirable fraction)	NE	10 (total dust), 5 (respirable fraction)	NE	NE	NE
Methyl Paraben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Mono & di Glycerides	67701-32-0	NE	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Sodium Lauryl Sulfate	151-21-3	NE	NE	NE	NE	NE	NE	NE	NE
Stearyl Alcohol	112-92-5	NE	NE	NE	NE	NE	NE	NE	NE
Tertiary Butylhydroquinone Exposure limits are for quinine (CAS# 106-51-4)	1948-33-0	0.44	NE	0.4	NE	0.4	NE		DFG MAKs: Danger of Sensitization of the Skin DFG Germ Cell Mutagen Cat. 3B Carcinogen: IARC-3, MAK-3B
Water	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE
White Ceresin Wax	8001-75-0	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.

HYPROMELLOSE:
Russia: STEL = 10 mg/m^3, JUN 2003

METHYL PARABEN:
Russia: STEL = 4 mg/m^3, 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

PROPYLENE GLYCOL (continued):
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), 2005
United Kingdom: TWA = 150 ppm (474 mg/m^3) (total vapor), 2005

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

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: Cream.
COLOR: Creamy white to off-white.
ODOR: Sight 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, Estradiol:

FORM: Crystalline solid.
COLOR: White.
MOLECULAR WEIGHT: 272.37
MOLECULAR FORMULA: $C_{18}H_{24}O_2$
ODOR: Odorless.
ODOR THRESHOLD: Odorless.
BOILING POINT @ 760 mmHg: 445.9°C (445.9°F) [predict.]
MELTING POINT: 178.5°C (353.3°F)
VAPOR PRESSURE (air = 1) @ 25°C: 0 mmHg [predict.]
SPECIFIC GRAVITY (water = 1): 1.171 g/cm^3
EVAPORATION RATE (nBuAc = 1): Not applicable.
FLASH POINT: 209.6°C (409.3°F) [predict.]
SOLUBILITY IN WATER @ 27°C: 3.90 mg/L
pH: Not available.

OTHER SOLUBILITIES: Very soluble in acetone, ethanol, dioxane; freely soluble in alcohol; soluble in acetone, dioxane, other organic solvents; solutions of fixed alkali hydroxides; sparingly soluble in vegetable oils.

COEFFICIENT WATER/OIL DISTRIBUTION @ 20°C: Log P: 4.146 [predict.]; Log Kow = -4.01

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, sodium 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, 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: If vapors, mists, or sprays are inhaled, they may cause coughing and temporary bronchial irritation. Symptoms are generally alleviated upon breathing fresh air.

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: Absorption of hormones through the skin may contribute to the effects of exposure as described in "Other Potential Health Effects".

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.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effects reported include headache, breast pain, irregular vaginal bleeding or spotting, stomach/abdominal cramps, bloating, nausea and vomiting, hair loss. May be absorbed through the skin. Chronic exposure may cause temporary impairment of fertility in both genders; interference with egg and sperm production. In men, exposure to female hormones has been associated with testicular atrophy, increased risk of prostate cancer, gynecomastia, loss of libido and potency. Can cause fetal harm in pregnancy, as an estrogen. Long-term therapeutic use can cause adverse effects on cardiovascular system with a greater risk for cigarette smokers. Limited evidence of carcinogenic effect; prolonged therapy poses a greater risk of cancer in post-menopausal women. Other effects can include high blood pressure, liver problems, high blood sugar, fluid retention, enlargement of benign tumor ('fibroids') of the uterus, spotty darkening of the skin, especially on the face and vaginal yeast infection.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS (continued): Prolonged therapeutic use increases the potential for gallbladder disease, eye disorders, endometrial, ovarian and breast cancer in certain individuals as well as serious cardiovascular effects (with a greater risk for cigarette smokers). Jaundice can occur in persons with impaired liver function. Estrogens may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine or porphyria (inherited neurological or skin conditions), systemic lupus erythematosus, and non-cancerous liver tumors. Exposure to female hormones in men can cause testicular atrophy, loss of libido and potency, gynecomastica (the abnormal growth of breast tissue), infertility from decrease in FSH and subsequent effects on sperm maturation. Changes in FSH levels affect the ovulatory cycle in women which may lead to decreased fertility. These effects may also be experienced from occupational exposure. Additional effects seen in therapeutic use have included the following.

- ***Body as a Whole:*** Increase or decrease in weight, swelling.
- ***Cardiovascular System:*** Deep and superficial venous thrombosis, pulmonary embolism, swelling of veins due to blood clot, heart attack, stroke, increase in blood pressure.
- ***Central Nervous System:*** Headache, migraine, dizziness, mental depression, involuntary movement disorder, nervousness, mood disturbances, irritability, exacerbation of epilepsy, dementia.
- ***Eyes:*** Retinal vascular thrombosis, intolerance to contact lenses.
- ***Gastrointestinal System:*** Nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, increased incidence of gallbladder disease, pancreatitis, enlargement of hepatic hemangiomas.
- ***Hypersensitivity Reactions:*** Facial swelling, anaphylactoid/anaphylactic reactions.
- ***Metabolic System:*** Aggravation of porphyria (rare inherited or acquired disorders of certain enzymes that normally participate in the production of porphyrins and heme), reduced carbohydrate tolerance, low blood calcium, increased triglycerides.
- ***Musculoskeletal System:*** Joint pain, leg cramps.
- ***Reproductive System:*** Fetal harm, changes in libido, breast tenderness, enlargement, pain, nipple discharge, spontaneous flow of milk from breast, fibrocystic breast changes, breast cancer. Changes in vaginal bleeding pattern and abnormal withdrawal bleeding or flow, breakthrough bleeding, spotting, abnormally painful cramps, increase in size of uterine leiomyomata, vaginitis, including vaginal candidiasis, change in amount of cervical secretion, changes in cervical ectropion, application site reactions of vulvovaginal discomfort including burning and irritation, genital pruritus, ovarian cancer, endometrial hyperplasia, endometrial cancer.
- ***Respiratory System:*** Exacerbation of asthma.
- ***Skin:*** Patchy brown or dark brown skin discoloration, that can be persistent, tissue itching, swelling, lesions, joint aches, tender, red bumps (nodules) under the skin, hemorrhagic eruption, loss of scalp hair, overgrowth of hair, itching, hives, rash.

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

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.

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

SENSITIZATION OF PRODUCT: No specific information available. Sensitization effects have been reported from therapeutic use of estrogens.

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.

ESTRADIOL:

TDLo (Oral-Human) 2.352 mg/kg/12 weeks-intermittent: Kidney/Ureter/Bladder: other changes in urine composition, other changes; Biochemical: Metabolism (Intermediary): other proteins

TDLo (Oral-Woman) 1.12 mg/kg/4 weeks-intermittent: Endocrine: changes in gonadotropins, estrogenic

TDLo (Oral-Woman) 0.24 mg/kg/6 days-intermittent: Lungs, Thorax, or Respiration: other changes; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

ESTRADIOL (continued):

TDLo (Oral-Woman) 1.2 mg/kg/8 weeks-intermittent: Blood: change in clotting factors

TDLo (Oral-Woman) 4400 µg/kg: female 31 week(s) pre-mating: Reproductive: Fertility: other measures of fertility

TDLo (Skin-Woman) 4 µg/kg/36 hours: Kidney/Ureter/Bladder: other changes in urine composition; Biochemical: Metabolism (Intermediary): effect on cyclic nucleotides

TDLo (Skin-Woman) 0.07 mg/kg/5 weeks-intermittent: Endocrine: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol)

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

Long-term continuous administration of estrogen, with and without progestin, in women with and without a uterus, has shown an increased risk of endometrial cancer, breast cancer, and ovarian cancer. Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, uterus, cervix, vagina, testis, and liver.

Estradiol is listed by agencies tracking the carcinogenic potential of chemical compounds as follows.

IARC-2B (Possibly Carcinogenic to Humans)

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL OF COMPONENTS (continued): In post-menopausal therapy, estrogens are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

IARC-1 (Carcinogenic to Humans); NTP-K (Known to be 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 Estradiol in pregnant women; Estradiol can 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 X (Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits).

Mutagenicity: In tests involving the Tertiary Butylhydroquinone component, both chromosome loss and breakage are induced. Reactive oxygen species contribute to the chromosomal breakage induced by Tertiary Butylhydroquinone but the observed chromosomal loss appears to result from other mechanisms such as an interference of quinone metabolites with spindle formation. The following human mutation data are available for the Estradiol active component.

Micronucleus Test (Human Lymphocyte) 5 µmol/L
Micronucleus Test (Human Cells-Not Otherwise Specified) 8 mg/L
Micronucleus Test (Human Ascites Tumor) 0.1 nmol/L/30 hours
Micronucleus Test (Human Lymphocyte) 8 mg/L/22 hours
Micronucleus Test (Human Fibroblast) 2 mg/L
Micronucleus Test (Human Cells-Not Otherwise Specified) 316 µmol/L/3 hours
Unscheduled DNA Synthesis (Human Mammary Gland) 10 nmol/L
DNA Inhibition (Human Lymphocyte) 10 µmol/L
Mutation Test Systems-Not Otherwise Specified (Human Fibroblast) 20 mg/kg
Cytogenetic Analysis (Human Lymphocyte) 1 mg/L
Cytogenetic Analysis (Human Lymphocyte) 2 mg/L/22 hours
Cytogenetic Analysis (Human Cells-Not Otherwise Specified) 2 mg/L
Sister Chromatid Exchange (Human Lymphocyte) 1 mg/L
Sex Chromosome Loss and Non-Disjunction (Human Fibroblast) 20 mg/L
Specific Locus Test (Human Mammary Gland) 1 mmol/L/2 weeks
DNA Damage (Human Lymphocyte) 50 µmol/L/30 minutes
DNA Damage (Human Sperm) 50 µmol/L/1 hour
DNA Damage (Human Ascites Tumor) 100 nmol/L/24 hours
DNA Damage (Human Mammary Gland) 100 nmol/L/24 hours
DNA Damage (Human Liver) 0.316 mmol/L/48 hours
DNA Damage (Human Liver) 0.1 mmol/L/48 hours

Embryotoxicity/Teratogenicity: No specific information available.

Reproductive Toxicity: No fertility studies available for the product. Estrogen administration to nursing mothers has been shown to decrease the quantity and quality of the milk. Detectable amounts of estrogens have been identified in the milk of mothers receiving this drug. Because of the potential for serious 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. The following information is for the active ingredient.

ESTRADIOL: Using a Drummer soil from Indiana (pH 7.1, 2.91% organic carbon, 21% clay, 13% sand, 66% silt), a log Koc of 3.45 (Freundlich constant Kd 83.2) was measured(1), corresponding to a Koc of 3,000. According to a classification scheme, this estimated Koc value suggests that Estradiol is expected to be immobile in soil. Kd values of 476 have been reported for Estradiol in activated sludge wastewater treatment systems; it was estimated that as much as 66% of Estradiol is absorbed to sludge and 0.24% sorbed to suspended particles during waste water treatment. Estradiol sorption was shown to increase with the amount of incorporated organic waste. In soils with an extensive history of organic waste treatments, soil organic carbon content is the controlling factor for estrogen sorption.

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 for the active ingredient.

ESTRADIOL: If released to air, an estimated vapor pressure of 6.4X10-9 mm Hg at 25°C indicates Estradiol will exist solely in the particulate phase in the atmosphere. Particulate-phase Estradiol will be removed from the atmosphere by wet or dry deposition. Estradiol irradiated with a xenon arc lamp exhibited a photo-degradation half-life of 2 hours in river water and 41.7 hours in air-saturated purified water, and therefore Estradiol may be susceptible to direct photolysis by sunlight. If released to soil, Estradiol is expected to have no mobility based upon an estimated Koc of 30,000. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 3.6X10-11 atm-cu m/mole. A 6% mineralized of Estradiol in 5 days after application to a agricultural soil microcosm suggests biodegradation is not an important environmental fate process. If released into water, Estradiol is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is not expected to be an important fate process based upon this compound's estimated Henry's Law constant. Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bioaccumulation potential. The following information is for the active ingredient.

ESTRADIOL: An estimated BCF of 200 was calculated in fish for Estradiol, using a log Kow of 4.01 and a regression-derived equation. An estimated log BCF of 2.65 was calculated in fish for Estradiol using a food-web model, corresponding to a BCF of 450. According to a classification scheme, this BCF suggests the potential for bioconcentration in aquatic organisms is high, provided the compound is not metabolized by the organism.

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. The following aquatic toxicity data are available for the some ingredients. Only select data for Estradiol are provided in this SDS. Contact Actavis for more information.

ESTRADIOL:

LC_{50} (*Daphnia magna* Water flea, Water flea) 48 days = 2970 µg/L
EC_{50} (*Daphnia magna* Water flea, age < 24 hr neonate newly released) 48 hours = 2040 µg/L (
EC_{50} (Danio rerio Zebra danio, age 6-8 month adult, female) 3 weeks = 140-145 mg/L
EC_{50} (*Pimephales promelas* Fathead minnow, age 12-18 month sexually mature female) 19 days = 0.12 µg/L

ESTRADIOL (continued):

IC_{50} (*Oryzias latipes* Medaka, eggs) 72 hours = 470 µg/L (95% confidence interval: 360-580 µg/L)
LC_{50} (*Oryzias latipes* Medaka, adult female) 72 hours = 3500 µg/L (95% confidence interval: 2700-4300 µg/L)
LC_{50} (*Oryzias latipes* Medaka, age 4 month sexually mature) 96 hours = 0.002 µg/L

12. ECOLOGICAL INFORMATION (Continued)

ECOTOXICITY (continued):

TERTIARY BUTYLHYDROQUINONE:
LC_{50} (bluegill) 96 hours = 3.94 mg/L
LC_{50} (catfish) 96 hours = 4.31 mg/L
LC_{50} (Daphnia) 96 hours = 4.70 mg/L

TERTIARY BUTYLHYDROQUINONE (continued):
LC_{50} (fathead minnow) 96 hours = 5.10 mg/L
LC_{50} (goldfish) 96 hours = 5.72 mg/L
LC_{50} (mosquitofish) 96 hours = 5.19 mg/L
LC_{50} (rainbow trout) 96 hours = 4.00 mg/L

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

ADDITIONAL 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): The Estradiol component of this product is on the California Proposition 65 lists. WARNING! This product contains a compound known to the State of California to cause cancer.

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: 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.

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): WARNING! CANCER HAZARD. MAY CAUSE CANCER THROUGH THERAPEUTIC USE. MAY BE HARMFUL IF SWALLOWED. MAY BE ABSORBED THROUGH THE SKIN. CHRONIC EXPOSURE MAY CAUSE TEMPORARY IMPAIRMENT OF FERTILITY IN BOTH GENDERS. MAY CAUSE HARM TO THE FETUS DURING PREGNANCY. LONG-TERM THERAPEUTIC USE CAN CAUSE ADVERSE EFFECTS ON CARDIOVASCULAR SYSTEM WITH A GREATER RISK FOR CIGARETTE SMOKERS. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. 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.

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.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Estradiol: This is a self-classification.

Classification: Carcinogenic Category 2, Reproductive Toxicity Category 1B, Specific Target Organ Toxicity (Cardiovascular System) Repeated Exposure Category 2, Effects on or Via Lactation

Hazard Statements: H351: Suspected of causing cancer. H360Df: May damage the unborn child. Suspected of damaging fertility. H373: May cause damage to organs, including cardiovascular system, through prolonged or repeated exposure. H362: May cause harm to breast-fed children.

Sodium Lauryl Sulfate: This is a self-classification.

Classification: Acute Oral Toxicity Category 4, Eye Irritation Category 2A

Hazard Statements: H302: Harmful if swallowed. H319: Causes serious eye irritation.

Tertiary Butylhydroquinone: This is a self-classification.

Classification: Germ Cell Mutagen Category 2, Acute Oral Toxicity Category 4

Hazard Statements: H341: Suspected of causing genetic effects. H302: 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.

CLASSIFICATION OF COMPONENTS:

67/548/EEC:

Estradiol: This is a self-classification.

Hazard Classification: Carcinogenic Category 3, Reproductive Toxicity Category 2, Reproductive Toxicity Category 3, Harmful

Risk Phrases: R40: Limited evidence of a carcinogenic effect. R61: May cause harm to the unborn child. R62: Possible risk of impaired fertility. R33: Danger of cumulative effects. R64: May cause harm to breast-fed babies.

Sodium Lauryl Sulfate: This is a self-classification.

Hazard Classification: Harmful, Irritant

Risk Phrases: R22: Harmful if swallowed. R36: Irritating to eyes.

Tertiary Butylhydroquinone: This is a self-classification.

Hazard Classification: Germ Cell Mutagen Category 3, Harmful

Risk Phrases: R68: Possible risk of irreversible effects. R22: Harmful if swallowed.

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.

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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