



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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ESTRIOL

Catalog Number: 1254508

Revision Date:

November 21, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Estriol

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW - Cancer Suspect Agent. Reproductive Hazard.

Adverse Effects: Adverse effects of estrogens may include breast pain, tenderness, enlargement, lumps, or discharge; changes in menstrual bleeding; swelling of feet or lower legs; rapid weight gain; pain in stomach, sides, or abdomen; yellow eyes or skin; blood clots (characterized by severe or sudden headache; sudden loss of coordination; pains in chest, groin, or leg, especially calf; sudden shortness of breath; sudden slurred speech; sudden vision changes; and weakness or numbness in arm or leg); abdominal cramping or bloating; loss of appetite; nausea; vomiting; diarrhea; dizziness; headache; intolerance to contact lenses; and change in libido. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: n/f

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization and cancer.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, abnormal or undiagnosed genital or uterine bleeding, estrogen-dependent tumors, thrombophlebitis or thromboembolic disorders, hypercalcemia associated with bone or breast cancer, impaired liver function or jaundice, and porphyria.

Cross Sensitivity: n/f

Target Organs: Female reproductive system

For additional information on toxicity, see Section 11.

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SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Common Name: Estriol

Formula: C₁₈H₂₄O₃

Synonym: Oestriol

Chemical Name: Estra-1,3,5(10)-triene-3,16,17-triol, (16 α ,17 β)-

CAS: 50-27-1

RTECS Number: KG8225000

Chemical Family: Steroid

Therapeutic Category: Estrogen

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation and systemic effects. Avoid inhalation. Remove to fresh air. This material can be absorbed through inhalation.

Eye: May cause irritation. Avoid exposure. Flush with copious quantities of water.

Skin: May cause irritation and systemic effects. Avoid contact. Flush with copious quantities of water. This material can be absorbed through the skin.

Ingestion: May cause irritation. Avoid ingestion. Flush out mouth with water. Estrogens are absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

SECTION 5 - FIREFIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it
CAUTION: HAZARDOUS CHEMICAL WASTE.

SECTION 7 - HANDLING AND STORAGE

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety goggles or glasses

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: Small white crystals, or white to cream crystalline powder; odorless

Odor Threshold: n/f

pH: n/f

Melting Range: 280 - 285° C (crystal structure changes at 270° C)

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: 1.27

Solubility in Water: Insoluble

Fat Solubility: Soluble in vegetable oils

Other Solubility: Soluble in acetone, in chloroform, in dioxane, and in ether; sparingly soluble in alcohol; freely soluble in pyridine and in solutions of fixed alkali hydroxides

Partition Coefficient: n-octanol/water: 2.45

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₁₈H₂₄O₃

Molecular Weight: 288.38

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SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to light.

Incompatibilities: Oxidizing agents

Decomposition Products: When heated to decomposition material emits acrid smoke and irritating fumes. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: >2 grams/kg

Oral Mouse: LD50: n/f

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** Yes **OSHA:** No

Other Carcinogenicity Data: Independent studies have shown an increased risk of endometrial cancer in post-menopausal women placed on estrogen therapy (including estriol) without progestin for prolonged periods. Whether the use of systemic estrogens increases the risk of breast cancer in post-menopausal women is unresolved. Estrogens have been associated with breast cancer in men. Subcutaneous implantation of estriol in castrated mice and in rats and hamsters increased the incidence and accelerated the appearance of mammary tumors in both male and female mice and produced kidney tumors in hamsters.

Mutagenicity Data: Estriol induced sister-chromatid exchanges in human lymphocytes in vitro, but was not mutagenic in the Salmonella Ames assay, with or without activation.

Reproductive and Developmental Effects: Studies suggest an association between birth defects in the fetus and maternal use of some estrogens during pregnancy. The male fetuses of rats administered 0.1 or 1 micromole of estriol during pregnancy had shortened urethral length.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: n/f

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Place material in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

ESTRIOL**Catalog Number:** 1254508**Revision Date:**November 21, 2006

U.S. Regulatory Information: n/f**International Regulatory Information:** EINECS # 200-022-2
Hazard Code: T
Risk Phrases: R45, R60, R61
Safety Phrases: S45, S53

SECTION 16 - OTHER INFORMATION

Revision: 21-Nov-06**Previous Revision Date:** 22-May-02