

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification**Product Name** ESTRADIOL USP HEMIHYDRATE MICRONIZED**Commercial Name** N/A**Product Use** N/A**Restrictions On Use** N/A**Product Code** 30-4981**Company** PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300**Section 2: Hazard(s) Identification****OSHA Haz Com:** Carcinogenicity Category 1A Reproductive toxicity Category 1**CFR 1910.1200****Signal Word** DANGER**Hazard Statement(s)** May cause cancer. May damage fertility or the unborn child.**Pictogram(s) or Symbol(s)****Precautionary Statement(s):**

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Estradiol Hemihydrate
% By Weight	N/A
CAS#	35380-71-3
Molecular Weight	N/A
Chemical Formula	N/A
Synonym(s)	N/A

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Estradiol Hemihydrate	35380-71-3	N/A	N/A	N/A

Safety Data Sheet

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Section 4: First-Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Symptoms/Effects	
Acute	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Delayed	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials**Unsuitable Extinguishing Media**

Not available

Products of Combustion

No unusual fire or explosion hazards noted.

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Cool containers exposed to flames with water until well after the fire is out.

Section 6: Accidental Release Measures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Prevent entry into waterways, sewer, basements or confined areas. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA 0.1 micrograms/m ³
Engineering Controls	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Personal Protection

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene consideration: Handle in accordance with good industrial hygiene and safety practice. Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 9: Physical and Chemical Properties

Appearance	White. Cream. Crystalline powder. Crystals Solid.		
Odor	Odorless		
Odor Threshold	N/A		
Melting Point	343.4 - 356 °F (173 - 180 °C)	pH	N/A
Freezing Point	N/A	Vapor Pressure	N/A
Boiling Point/Range	N/A	Vapor Density	N/A
Decomposition temperature	N/A	Viscosity	N/A
Partition Coefficient: n-octanol/water	3.3	Evaporation Rate	N/A
Flash Point	N/A	Autoignition temperature	N/A
Flammability	N/A	Flammability or Explosive Limits:	
		Lower	N/A
		Upper	N/A
Solubility(ies)	Practically insoluble in water.		
Other	Acetone: Soluble. Chloroform: Soluble. Dioxane: Soluble. Ethanol: Soluble. Vegetable oils: Sparingly soluble. Chemical family Steroid. Molecular formula C ₁₈ H ₂₄ O ₂ . 1/2H ₂ O Molecular weight 281.39		

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions
Hazardous Polymerization	No dangerous reaction known under conditions of normal use
Conditions to Avoid	Contact with incompatible materials
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

Section 11: Toxicological Information

RTECS	N/A
Acute Toxicity	Oral LD ₅₀ Mouse > 4000 mg/kg Rat > 4000 mg/kg
Skin Corrosion/Irritation	N/A
Serious Eye Damage/Irritation	N/A
Respiratory or Skin Sensitization	N/A
Germ Cell Mutagenicity	N/A
Carcinogenicity	May cause cancer
Reproductive Toxicity	May damage fertility or the unborn child
Routes of Entry	Skin. Ingestion.

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Symptoms Related to Exposure

Estrogens: Menstrual irregularities. Fluid retention. Blood clots. Mood or mental changes. Full or tender breasts. Feminization effects in males. Gastrointestinal disturbances.

Potential Health Effects

N/A

Target Organ(s)

Not available.

Section 12: Ecological Information**Ecotoxicity**

Aquatic Fish LC50 Fish 0.002 µg/l, 96 hours

Persistence and Degradability

No additional information available

Bioaccumulative Potential

Octanol/water partition coefficient log Kow 3.3

Mobility in Soil

No additional information available

Other Adverse Effects

No additional information available

Section 13: Disposal Considerations**Waste Disposal**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Disposal of Container

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations

N/A

Section 14: Transport Information**DOT Classification**

DOT Not regulated as dangerous goods

Section 15: Regulatory Information**Regulations**

US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Carcinogenicity Reproductive toxicity Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Other

N/A

Section 16: Other Information



Safety Data Sheet

30-4981

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N/A