



Humco Holding Group, Inc.  
7400 Alumax Dr  
Texarkana TX 75501 USA  
800-662-3435  
cs@humco.com  
www.humco.com

24-Hour Emergency Number (CHEMTREC)  
USA- 800-424-9300

All non-emergency calls should be directed to  
Customer Service at 800-662-3435

**NAME: ESTRADIOL HEMIHYDRATE, USP**

**SDS NO. 8065**

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Estradiol Hemihydrate, USP

**Synonyms:** 8R,9S,13S,14S,17S)-13-methyl-6,7,8,9,11,12,14,15,16, 17-decahydrocyclopenta  
[a]phenanthrene-3,17-diol

**Recommended Use:** Active Pharmaceutical Ingredient

**Manufacturer by:** Humco Holding Group, Inc.

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## 2. HAZARD IDENTIFICATION

<b>Pictogram:</b>	
<b>Classification:</b>	<p>Acute Toxicity:Inhalation, Category 4 Acute Toxicity:Oral. Category 4 Acute Toxicity:Skin.Category 4 Carcinogenicty, Category 2 Toxic To Reproduction.Category 18 Aquat ic Toxicity (Acute). Category 1 Toxic To Reproduction, Effects on or via lactation</p>

<b>Signal Word:</b>	Danger
<b>Hazard Statements:</b>	Harmful if inhaled Harmful if swallowed Harmful in contact with skin Suspected of causing cancer May damage fertility or the unborn child Very toxic to aquatic life May cause harm to breast-fed children
<b>Precautionary Statements</b>	Avoid breathing dust/ fume/gas/mist/vapors/spray. Wash hands thoroughly after handling. Wear protective gloves/clothing and eye/face protection as specified by the manufacturer/supplier or the competent authority. Take off contaminated clothing and wash it before reuse. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Avoid release to the environment - if this is not the intended use. Avoid contact during pregnancy/while nursing. Do not breathe dust/fume/gas/mist/vapors/spray.

### 3. COMPOSITION / INGREDIENTS

CHEMICAL NAME	CAS#
ESTRADIOL, USP	35380-71-3

### 4. FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS: Not expected to present a significant hazard under anticipated conditions of normal use.

## 5. FIRE-FIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO<sub>2</sub> or water spray. Large fire: dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition.

Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS: Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight, light-resistant containers.

## 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

National occupational exposure limits  
United States

Components	IARC	OSHA	ACGIH	AIHA WHEEL
Estradiol 50-28-2	N/L	N/L	N/L	N/L

EXPOSURE GUIDELINES: Consult local authorities for provincial or state exposure limits

PERSONAL PROTECTIVE EQUIPMENT: Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS: Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White powder	<b>Upper/Lower Flammability:</b>	Not determined
<b>Odor:</b>	Not determined	<b>Vapor Pressure</b>	Not determined
<b>Odor Threshold:</b>	Not determined	<b>Vapor Density:</b>	Not determined
<b>pH:</b>	Not determined	<b>Relative Density:</b>	Not determined
<b>Melting point /Freezing Point:</b>	176 - 180 °C (349 - 356 °F)	<b>Solubilities:</b>	Not determined
<b>Boiling point/range:</b>	Not determined	<b>Partition coefficient: n-octanol/water:</b>	Not determined
<b>Flash point</b>	Not determined	<b>Auto-ignition temperature</b>	Not determined
<b>Evaporation rate</b>	Not determined	<b>Decomposition Temperature:</b>	Not determined
<b>Flammability:</b>	Not determined	<b>Viscosity</b>	Not determined

## 10. STABILITY AND RACTIVITY

REACTIVITY: Not established

STABILITY: Stable under recommended storage conditions

MATERIALS TO AVOID: Not determined

HAZARDOUS DECOMPOSITION PRODUCTS: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION: Will not occur

POSSIBILITY OF HAZARDOUS REACTION: Not established

CONDITIONS TO AVOID: Moisture, sunlight and extreme temperatures

## 11. TOXICOLOGICAL INFORMATION

Acute toxicity: No data available

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation: No data available

Serious eye damage/eye irritation: No data available

Respiratory or skin sensitization: No data available

Germ cell mutagenicity

The National Toxicology Program (Tenth Report on Carcinogens) has determined that steroidal estrogens are known to be human carcinogens based on sufficient evidence of carcinogenicity in humans, which indicates a causal relationship between exposure to steroidal estrogens and human cancer. This is or contains a component that has been reported to be carcinogenic based on its IARC, OSHA, ACGIH, NTP, or EPA classification.

Suspected human carcinogens

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: Known to be human carcinogen (Estradiol)

NTP: Known to be human carcinogen (Estradiol)

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Suspected human reproductive toxicant Damage to fetus cannot be excluded.

Known human reproductive toxicant Effects on or via lactation May damage fertility. Suspected of damaging the unborn child.

Specific target organ toxicity - single exposure: No data available

Specific target organ toxicity - repeated exposure: No data available

Aspiration hazard: No data available

Additional Information

RTECS: KG2975000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Liver - Irregularities - Based on Human Evidence

## 12. ECOLOGICAL INFORMATION

<b>Acute or chronic aquatic toxicity:</b>	No specific information available, but material is not intended to be released to the environment.
<b>Chemical degradation:</b>	Not determined.
<b>Biodegradation:</b>	Not determined.
<b>Bioaccumulation potential</b>	Not determined.
<b>Adsorption studies or leaching studies:</b>	Not determined.
<b>Other adverse effects</b>	Not determined.

### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local laws and regulations. Avoid release into environment.

### 14. TRANSPORT INFORMATION

<b>DOT Hazard Classification:</b>	NOT HAZARDOUS MATERIAL
<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group number:</b>	Not applicable
<b>Environmental hazards:</b>	Not applicable
<b>Special precautions:</b>	Do not freeze, avoid extreme heat

### IATA TRANSPORT INFORMATION

Not Regulated
Not Dangerous
Not Hazardous
Not Restricted For Transport by IATA

### 15. REGULATORY INFORMATION

Not determined

### 16. OTHER INFORMATION

The information in this SDS is considered current and reliable. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal are beyond Humco's control, it is the responsibility of the user to determine safe conditions for use and to assume liability for loss, damage, or expenses arising from improper use. No warranty expressed or implied regarding the product described herein will be created by or inferred from any statement or omission. Various agencies may have specific regulations concerning the transportation, handling,

**storage, use or disposal of this product which may not be reflected in the SDS. The user should review these regulations to ensure full compliance.**