SAFETY DATA SHEET

1. Identification

Product identifier **Equilin**

Other means of identification

Catalog number 1238002

Chemical name Estra-1,3,5(10),7-tetraen-17-one, 3-hydroxy-

Synonym(s) 7-Dehydroestrone

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Carcinogenicity Category 1A
Reproductive toxicity Category 1

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement May cause cancer. May damage fertility or the unborn child.

Precautionary statement

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.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Equilin	7-Dehydroestrone	474-86-2	100

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 SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed	Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed	In acute single overdosage, toxicity is unlikely and treatment to ease gastrointestinal irritation is all that is required. In chronic toxicity, monitor for severe signs of toxicity and treat symptomatically. [Poisindex 2009]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe 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. Use of a designated area is recommended for handling of potent materials.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to creamy-white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	446 - 464 °F (230 - 240 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Sparingly soluble.
Partition coefficient (n-octanol/water)	2.9 = log Pow
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Steroid.
Molecular formula	C18H20O2
Molecular weight	268.35
Solubility (other)	Soluble in alcohol, in dioxane, in acetone, and in ethyl acetate.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.

Incompatible materials	Oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Due to lack of data the classification is not possible.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Estrogens: In females and males: Nausea. Vomiting. Abdominal pain. Diarrhea. Headache. Dizziness. Drowsiness. Vision problems. Breast pain. Vaginal bleeding. Change in sex drive. Gallstones. Blood clots. Joint pain. Mood disturbances. In females: Full or tender breasts. Menstrual changes. In males: Breast enlargement or other feminizing effects.
Delayed and immediate effects of exposure	Estrogens: Fluid retention. Jaundice. Stroke. Deep vein thrombosis. Increase in blood pressure. Cancer.
Medical conditions aggravated by exposure	Estrogens: Abnormal genital bleeding. Breast cancer. Estrogen-dependent tumors. Endometriosis. Blood clots. Liver impairment. Kidney impairment. Porphyria. Asthma. Epilepsy. Migraine. Cardiovascular disease. Cerebrovascular disease. Hypoglycemia. Hypocalcemia. Systemic lupus erythematosus. High blood pressure. Diabetes mellitus. Uterine fibroids. Hypertriglyceridemia. Hypoparathyroidism.
Acute toxicity	Due to lack of data the classification is not possible.
Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible.

Mutagenicity

Unscheduled DNA synthesis assay in rat hepatocytes
Result: Negative.

Carcinogenicity	May cause cancer. IARC: Group 1; Carcinogenic to humans. NTP: Known to be a human carcinogen. In humans, long-term use of estrogens is associated with an increased risk of cancer of the endometrium, breast (male and female), and ovary. In animal studies, long-term administration of estrogens increased the incidence of cancer of the breast, cervix, vagina, uterus, testis, pancreas, and liver.

Carcinogenicity study, Administered by subcutaneous implantation.
Result: Increased incidence in kidney carcinomas.
Species: Hamster
Test Duration: 9 months

Reproductive toxicity	May damage fertility or the unborn child. Studies suggest an association of estrogen usage with birth defects including heart defects, eye and ear abnormalities, and Down's syndrome.
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Not available.

Hazardous waste code	Not regulated.
Waste from residues / unused products	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).
Contaminated packaging	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.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Schedule III - 4000
Food and Drug Administration (FDA)	Not regulated.
US state regulations	WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	04-01-2009
Revision date	11-26-2013
Version #	02

Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.