



SAFETY DATA SHEET

1. Identification

Product identifier: Estradiol Hemihydrate
Chemical name: Estra-1,3,5(10)-triene-3,17-diol, (17beta)-
Synonym(s): Estradiol-17-beta
Recommended use of the chemical and restrictions on use: For further manufacturing, process or repacking

Manufacturer information:

Company name: Zhejiang Xianju Pharmaceutical Co., Ltd
Address: No.1 Xianyao Road, Xianju, China, 317300
Telephone: +86-576-87731117
Fax: +86-576-87731117
Website: www.xjpharma.com
E-mail: regulation@xjpharma.com
Emergency phone number (for both supplier and manufacturer): +86-576-87778661

2. Hazard(s) identification

Classification of the substance or mixture

Physical hazards: Not classified
Health hazards: Carcinogenicity Category 1A
Reproductive toxicity Category 1

OSHA hazard(s): Not classified

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

Label elements

Pictograms:



Signal word: Danger

Precautionary statements:

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: Preserve in tight, light-resistant container. Store at 0 to 30°C
Disposal: Dispose of contents/container in accordance with local/regional/national/

international regulations.

Other hazards which do not result in classification: Not classified.

3. Composition/information on ingredients

Molecular formula: C₁₈H₂₄O₂ · 1/2H₂O
Molecular weight: 281.39
Chemical name: Estradiol Hemihydrate
CAS number: 35380-71-3
Concentration: 100%

4. First-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Remove and isolate contaminated clothing and shoes. Rinse skin with water/shower. Get medical attention if irritation develops and persists. For minor skin contact, avoid spreading material on unaffected skin.

Eye contact: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion: Do not induce vomiting without advice from poison control center. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms /effects, acute and delayed: Endocrine system effects.

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. 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: Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: No unusual fire or explosion hazards noted.

Special protective equipment and precautions for Wear suitable protective equipment.



firefighters:

Fire-fighting equipment/instructions: 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.

Specific methods: Use standard firefighting procedures and consider the hazards of other involved materials.

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. Clean surface thoroughly to remove residual contamination.

Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling: As a general rule, when handling, 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: Preserve in tight, light-resistant container. Store at 0 to 30°C

8. Exposure controls/personal protection

Exposure limit values	Industrial Use		
	Material	Type	Value
	Estradiol Hemihydrate	TWA	0.1 micrograms/m3

Biological limit values: No biological exposure limits noted for the ingredient(s).

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.

Individual protection measures, such as personal protective equipment:

Eye/face protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection 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. 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 respiratory protection and have an effective respirator program in place.

Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance: White or almost white crystalline powder.

Physical state: Solid.

Form: Powder.

Odor: Odorless

Odor threshold: Not available

pH: Not available

Melting point/ freezing point: 173-180 °C

Initial boiling point and boiling: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid, gas): Not available.

Upper/lower flammability or explosive limits:

Flammability limit	- Not available.
lower(%):	
Flammability limit	- Not available.
upper(%):	
Explosive limit - lower	Not available.
(%):	
Explosive limit - upper	Not available.
(%):	
Vapor pressure:	Not available.
Vapor density:	Not available.
Relative density:	Not available.
Solubility in water:	Practically insoluble.
Partition coefficient (n-octanol/water):	3.3
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Other information:	
Chemical family:	Steroid
Solubility (other):	Soluble in ethanol, in acetone, in dioxane, in chloroform, and in solutions of fixed alkali hydroxides; sparingly soluble in vegetable oils.

10. Stability and reactivity

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability:	Stable at normal conditions.
Possibility of hazardous reactions:	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.

11. Toxicological information

Information on likely routes of exposure:

Ingestion:	Based on information from therapeutic use, this material may cause Endocrine effects.
Inhalation:	Due to lack of data the classification is not possible.
Skin contact:	Based on information from therapeutic use, this material may cause Endocrine effects.
Eye contact:	Due to lack of data the classification is not possible.
Symptoms related to the	Estrogens: Menstrual irregularities. Fluid retention. Blood clots. Mood or

physical, chemical, and toxicological characteristics: mental changes. Full or tender breasts. Feminization effects in males. Gastrointestinal disturbances.

Information on

Acute toxicity

toxicological effects

Product

Species

Test Results

Estradiol Hemihydrate

Oral

Mouse

>4000 mg/kg

LD50

Rat

>4000 mg/kg

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/eye

Knowledge about health hazard is incomplete.

irritation

Carcinogenicity

May cause cancer.

Long term use of estrogens in humans has shown an increased risk of endometrial, breast and ovarian cancer. In certain animal species, long term continuous administration of estrogens increased the frequency of cancer of the breast, cervix, vagina, pancreas, testis, uterus and liver.

Reproductive toxicity

May damage fertility or the unborn child.

Studies suggest an association between congenital malformations in the fetus and maternal use of some estrogens during pregnancy

Specific target organ

Knowledge about health hazard is incomplete.

toxicity -single exposure

Specific target organ

Knowledge about health hazard is incomplete.

toxicity -repeated

exposure

12. Ecological information

Ecotoxicity:

Product

Species

Test results

Estradiol Hemihydrate

Aquatic

Fish

LC50 Fish

0.002 µg/l, 96 hours

Persistence and

No data is available on the degradability of this product.

degradability:

Bioaccumulative potential:

Not available.

Mobility in soil:

Not available.

Other adverse effects:

Not available.

13. Disposal considerations

Disposal instructions:

Dispose of contents/container in compliance with local/regional/national/international regulations

Local disposal

Dispose of in accordance with local regulations.



regulations:

- Hazardous waste code:** Not available.
- Waste from residues/
unused products:** 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).
- 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:** **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**
Not regulated.
- 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:** Not listed.
- SARA 311/312** Yes
- Hazardous chemical:**
- Other federal regulations:**
- Safe Drinking Water
Act (SDWA):** Not regulated.
- Food and Drug
Administration
(FDA):** Not regulated.
- US state regulations:** WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

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

- Issue date:** 01-06-2017
- Revision date:** 01-04-2019



浙江仙琚制药股份有限公司
ZHEJIANG XIANJU PHARMACEUTICAL CO., LTD.

Add: No.1 Xianyao Road, Xianju, Zhejiang, China, P.C: 317300

E-mail: regulation@xjpharma.com Tel: 86-576-87731117 Fax: 86-576-87731117

www.xjpharma.com

Version #: 02

Further information: Not available.