

Safety Data Sheet



Version: 1.0

Issued: 21 Dec 2021

1. Identification

Product Identifier	Estradiol Hemihydrate
Other means of identification	
Internal item number	82393-0109 82393-0110
CAS number	35380-71-3
Synonyms	Estradiol-17-beta * Dihydrofollicular hormone
Chemical name	Estra-1,3,5(10)-triene-3,17beta-diol hemihydrate

Relevant use and restrictions: No further information available.


Application of substance: Active pharmaceutical ingredient.

Manufacturer/Supplier information

Company name	Pharma Source Direct
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
Website	www.pharmasd.com

Emergency phone number Infotrac: 1-800-535-5053

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Carcinogenicity	Category 1A
	Reproductive toxicity	Category 1
Environmental hazards	Not classified	
OSHA defined hazards	Not classified	
Label elements		

Signal word	Danger
Hazard statement	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.

Safety Data Sheet



Hazards not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

3. Composition/Information on Ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Estradiol	Estradiol-17-beta Dihydrofollicular hormone	35380-71-3	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 ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
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	Water. Foam. Dry chemical or CO ₂ . 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 firefighters	Wear suitable protective equipment.

Safety Data Sheet



Version: 1.0

Issued: 21 Dec 2021

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

Cool containers exposed to flames with water until well after the fire is out.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

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.

7. Handling and Storage

Precautions for safe handling

As a general rule, 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.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material	Type	Value
Estradiol (CAS 35380-71-3)	TWA	0.1 micrograms/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate 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

Safety Data Sheet



Version: 1.0
Issued: 21 Dec 2021

exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

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 considerations

Handle in accordance with good industrial hygiene and safety practice. Pharmacological effects may be seen with occupational exposure. Procedures for any uses or quantities should be determined after an appropriate assessment.

9. Physical and Chemical Properties

Appearance

Appearance descriptions are general information and not specific to any lot.

Physical state

Solid.

Form

Crystalline powder. Crystals.

Color

White. Cream.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

343.4 - 356 °F (173 - 180 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Safety Data Sheet



Version: 1.0

Issued: 21 Dec 2021

Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Practically insoluble.
Solubility (other)	Acetone: Soluble. Chloroform: Soluble. Dioxane: Soluble. Ethanol: Soluble. Vegetable oils: Sparingly soluble.
Partition coefficient (n-octanol/water)	3.3
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Steroid
Molecular formula	C ₁₈ H ₂₄ O ₂ . 1/2H ₂ O
Molecular weight	281.39

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.
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

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Based on information from therapeutic use, this material may cause: Endocrine effects.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Based on information from therapeutic use, this material may cause: Endocrine effects.
Symptoms related to the physical, chemical, and toxicological characteristics	Estrogens: Menstrual irregularities. Fluid retention. Blood clots. Mood or mental changes. Full or tender breasts. Feminization effects in males. Gastrointestinal disturbances.
Information on toxicological effects	
Acute toxicity	

Safety Data Sheet



Product	Species	Test Results
Estradiol (CAS 35380-71-3)		
Oral		
LD50	Mouse	> 4000 mg/kg
	Rat	> 4000 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Local effects		
Skin irritation		
Result: Negative.		
Species: Human		
Skin irritation		
Result: Negative.		
Species: Rabbit		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Sensitization		
Result: Negative.		
Species: Guinea pig		
Organ: Skin		
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
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.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Estradiol (CAS 35380-71-3)	1 Carcinogenic to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)	Not regulated.	
US. National Toxicology Program (NTP) Report on Carcinogens		
Estradiol (CAS 35380-71-3)	Known To Be Human Carcinogen.	
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.	
Reproductivity		
0.8 - 35 mg/day Reproductivity, Feminization of male fetus genitalia.		
Species: Rat		
10 - 100 microgram/kg Reproductivity, Adverse effects on offspring survival and reproductive organ development.		
Species: Mouse		
Reproductivity, Adverse effects on offspring survival and reproductive organ development. NOEL=0.001mg/kg		
Species: Mouse		
Test Duration: 13 weeks		
Specific target organ toxicity -	Knowledge about health hazard is incomplete.	

Safety Data Sheet

**single exposure****Specific target organ toxicity - repeated exposure**

Knowledge about health hazard is incomplete.

Aspiration hazard

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

Further information

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological Information

Ecotoxicity**Product****Species****Test Results**

Estradiol (CAS 35380-71-3)

Aquatic

Fish LC50

Fish

0.002 µg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential**Octanol/water partition coefficient log Kow**

3.3

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions

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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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 dangerous goods.

IATA

Not regulated as dangerous goods.

Safety Data Sheet



Version: 1.0
Issued: 21 Dec 2021

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory Information

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.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Carcinogenicity
Reproductive toxicity

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.

Safe Drinking Water Act (SDWA)

Not regulated.

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.

International Inventories

Country(s) or region

Inventory name

On inventory (yes/no)*

Safety Data Sheet



Version: 1.0

Issued: 21 Dec 2021

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
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)	No
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
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
Unites 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)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other Information

Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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