

# Safety Data Sheet

acc. to OSHA HCS

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Printing date 05/05/2023

Reviewed on 05/05/2023

## 1 Identification

- **Product identifier**
- **Trade name: Estradiol Hemihydrate**  
**Estradiolum hemihydricum**
- **Article number:** 100456
- **CAS Number:**  
35380-71-3
- **EC number:**  
200-023-8
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

## 2 Hazard(s) identification

- **Classification of the substance or mixture**

Acute Toxicity - Oral 4	H302	Harmful if swallowed.
Acute Toxicity - Dermal 4	H312	Harmful in contact with skin.
Acute Toxicity - Inhalation 4	H332	Harmful if inhaled.
Sensitization - Respiratory 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Sensitization - Skin 1	H317	May cause an allergic skin reaction.
Germ Cell Mutagenicity 1A	H340	May cause genetic defects.
Carcinogenicity 1A	H350	May cause cancer.
Toxic to Reproduction 1A	H360-H362	May damage fertility or the unborn child. May cause harm to breast-fed children.

- **Label elements**

- **GHS label elements**

The substance is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger

- **Hazard statements**

Harmful if swallowed, in contact with skin or if inhaled.

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- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- May cause an allergic skin reaction.
- May cause genetic defects.
- May cause cancer.
- May damage fertility or the unborn child. May cause harm to breast-fed children.

· **Precautionary statements**

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Do not breathe dusts or mists.
- Avoid contact during pregnancy/while nursing.
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Use only outdoors or in a well-ventilated area.
- Contaminated work clothing must not be allowed out of the workplace.
- Wear protective gloves/protective clothing/eye protection/face protection.
- [In case of inadequate ventilation] wear respiratory protection.
- If swallowed: Call a poison center/doctor if you feel unwell.
- Rinse mouth.
- If on skin: Wash with plenty of water.
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- IF exposed or concerned: Get medical advice/attention.
- Specific treatment (see on this label).
- Take off contaminated clothing and wash it before reuse.
- If skin irritation or rash occurs: Get medical advice/attention.
- If experiencing respiratory symptoms: Call a poison center/doctor.
- Wash contaminated clothing before reuse.
- Store locked up.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMS-ratings (scale 0 - 4)**



- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**  
CAS: 35380-71-3 Estradiol Hemihydrate  
Estradiolum hemihydricum
- **Identification number(s)**
- **EC number:** 200-023-8

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## 4 First-aid measures

- **Description of first aid measures**
- **General information:**  
Seek medical treatment.  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Do not induce vomiting; immediately call for medical help.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Water spray  
Foam  
Fire-extinguishing powder  
Carbon dioxide  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**  
In case of fire, the following can be released:  
Carbon monoxide (CO)
- **Advice for firefighters**
- **Protective equipment:**  
Mouth respiratory protective device.  
Wear fully protective suit.  
Wear self-contained respiratory protective device.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Ensure adequate ventilation
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.  
Dispose of the collected material according to regulations.  
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

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- **Protective Action Criteria for Chemicals**
- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Thorough dedusting.  
Prevent formation of dust.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep receptacle tightly sealed.  
Store in a cool place.  
Store receptacle in a well ventilated area.  
Protect from exposure to the light.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the remaining constituent has no known exposure limits.  
At this time, the other constituents have no known exposure limits.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.  
Avoid contact with the eyes and skin.
- **Breathing equipment:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

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The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Crystalline powder

Color: White

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: 173–180°C (343.4–356°F)

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Product is not flammable.

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

Water: Not determined.

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- |   |  |
|---|--|
| · <b>Partition coefficient (n-octanol/water):</b> Not determined. |  |
| · <b>Viscosity:</b>   |  |
| <b>Dynamic:</b>   | Not applicable.                            |
| <b>Kinematic:</b>   | Not applicable.                            |
| · <b>Other information</b>  | No further relevant information available. |

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** Reacts with oxidizing agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Sensitization:**  
Sensitization possible through inhalation.  
Sensitization possible through skin contact.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.
- **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Water hazard class 3 (Self-assessment): extremely hazardous for water  
Danger to drinking water if even extremely small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

· <b>UN-Number</b> · DOT, IMDG, IATA	not regulated
· <b>UN proper shipping name</b> · DOT, IMDG, IATA	not regulated
· <b>Transport hazard class(es)</b> · DOT, ADN, IMDG, IATA · <b>Class</b>	not regulated
· <b>Packing group</b> · DOT, IMDG, IATA	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.

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- **National regulations:**
- **Information about limitation of use:**  
Workers are not allowed to be exposed to this hazardous material. Exceptions can be made by the authorities in certain cases.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:**  
Fagron US  
Quality Assurance
- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 05/05/2023
- **Abbreviations and acronyms:**  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
NIOSH: National Institute for Occupational Safety  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Acute Toxicity - Oral 4: Acute toxicity – Category 4  
Sensitization - Respiratory 1: Respiratory sensitisation – Category 1  
Sensitization - Skin 1: Skin sensitisation – Category 1  
Germ Cell Mutagenicity 1A: Germ cell mutagenicity – Category 1A  
Carcinogenicity 1A: Carcinogenicity – Category 1A  
Toxic to Reproduction 1A: Reproductive toxicity – Category 1A

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