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## 1 Identification of the substance/mixture and of the company/undertaking

· Informations to product No. 2483

· Product name:

### **Estradiol-Hemihydrat, mikronisiert, API** **17-beta-Estradiol**

· Supplier of the Product / responsible Company:

Caesar & Loretz GmbH

Herderstr. 31

40721 Hilden

Tel.: 02103/4994-0

Fax: 02103/32360

e-mail: info@caelo.de

· Emergency telephone:

Giftinformationszentrum Mainz

Langenbeckstr. 1, 55131 Mainz

Tel.: 06131/19240

· Relevant identified uses of the substance or mixture and uses advised against:

No further relevant information available.

· Application of the substance / mixture:

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

## 2 Hazards identification

· GHS-Labeling Elements:



· Signal word: Danger

· H-Phrases:

H360 May damage fertility or the unborn child

H351 Suspected of causing cancer

H372 Causes damage to organs through prolonged or repeated exposure

· P-Phrases:

P202 Do not handle until all safety precautions have been read and understood

P260 Do not breathe dust/fume/gas/mist/vapours/spray.


P281 Use personal protective equipment as required

P308+P313 IF exposed or concerned: Get medical advice/attention.

Repr. 1B

Carc. 2

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### 3 Composition / information on ingredients

**CAS-No. Substance name**

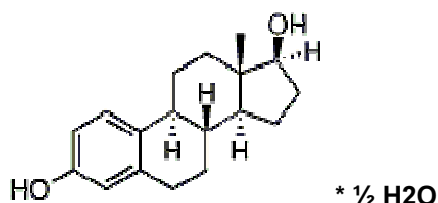
50-28-2 Estradiol-hemihydrate

• **EINECS-No.:** 200-023-8

• **REACH Reg. No.:** -

• **INCI-Name:** -

• **Chemical characterization:**



### 4 First aid measures

- **after inhalation:** Fresh. If feeling unwell continuously seek medical advice.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open. Seek medical advice.
- **after swallowing:** Drink water. Induce vomiting. Seek medical advice.

### 5 Fire-fighting measures


- **Suitable extinguishing media:** All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- **Specific hazards during fire fighting:** Combustible. In case of fire dangerous gases/vapours can be released.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Prevent extinguishing water from entering into ground water or surface waters.

### 6 Accidental release measures

- **Personal protective measures:** Avoid dust formation, Do not inhale dust.
- **Environmental protective measures:** Prevent from entering into surface water, the ground water system or soil.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

### 7 Handling and storage

- **Handling:** No special requirements.
- **Storage:**

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• **Requirements for storage areas and containers:**

Tightly closed. Store at a dry place. At room temperature ( +15°C to +25°C ).

• **Advices on common storage:**

TRGS 514 "Storage of toxic and very toxic substances ..."

• **Additional informations to storage conditions:** Keep container tightly closed.

## 8 Exposure controls / personal protective equipment

• **Personal protective equipment:**

• **General protective and hygiene measures:**

Wash hands before breaks and after work.

Avoid contact with eyes and skin.

• **Respiratory protection:** Dust protection mask

• **Hand protection:** Protection gloves.

• **Eye protection:** Safety glasses.

## 9 Physical and chemical properties

• **Form:** solid

• **Colour:** white

• **Odour:** Odourless

• **Melting point / melting range:** 176 - 179 °C (Decomposition)

• **Boiling point / boiling range:** not determined

• **Flash point:** not determined

• **Density:** not determined

• **Solubility in / Miscibility with**

• **Water:** (20 °C) 1,7 mg/l

• **log Pow:** See chapter 12

## 10 Stability and reactivity

• **Thermal decomposition / conditions to avoid:**

No decomposition during appropriate use.

Thermal decomposition: Above 147 °C

Decomposition energy: 128kJ/kg

• **Hazardous reactions:** The fine powder may cause dust explosion

• **Dangerous products of decomposition:** Carbon monoxide and carbon dioxide

• **Additional information:** The following applies to flammable organic substances and preparations: in correspondingly fine distribution, when whirled generally be assumed a dust explosion potential.

## 11 Toxicological information

• **Acute Toxicity**


LD50 (oral, mause): >4000mg/kg

LD50 (oral, rat): >4000mg/kg

• **Primary irritaton:**

• **on skin:** no data available

• **on eyes:** no data available

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- **Sensitization:** no sensitising known
- **Carcinogenity** All steroid hormones can stimulate the growth of hormone-dependent tissues and tumors.

- **Reproduction toxicity:**

TDLo	0,002 mg/kg (mouse) (Female (Subcutaneous) 8 d. after conception)
	0,2 mg/kg (rat) (Male (Parenteral) 1 d. premating)
	1,12 mg/kg (dog) (male (Parenteral) 16 w. premating)
	10 mg/kg (rat) (Female (Implant) 24 d. premating)
TDLo / Intramuscular	0,084 mg/kg (Monkey) (Female (14 d. premating))
	0,366 mg/kg (Female) (Pig ( 15-25 d. after conception))
	3,333 mg/kg (Female) (Pig (8-11 w. after conception))
TDlow	0,005-0,025 mg/kg (rat) (Female (Subcutaneous) 1 d. after conception)
	1 mg/kg (Female) (Intramuscular [5 d. premating])
	2,5 mg/kg (-) (Female rat (Intramuscular) 13 d. after conception)
	3,75 mg/kg (Male) (rat (Intramuscular) 15 d. premating)
TD (low)	0,0015 mg/kg (rat) (Female [3 d. premating])
	1,063 mg/kg (rat) (Female [21 d. postbirth])
TDLo	0,008 mg/kg (mouse) (Female (3-4 d. after conception))

## 12 Ecological information

- **Ecotoxical effects:**

EC50 (Daphnia magna): >100mg/l

EC50(Algen): >100mg/l

- **Additional information:** Prevent from entering into environmental waters, waste water or soil!
- **log Pow:** 4,03
- **Water hazard class:** WGK 2 (Self classification): hazardous for water.

## 13 Disposal considerations

- **Product:**
- **Recommendation:** Disposal according to local regulations as pharmaceutical waste.
- **Empty contaminated packaging:**
- **Recommendation:** Disposal according to the local regulations.

## 14 Transport informations

- **Land transport according to ADR:**


Not classified as dangerous in the meaning of transport regulations.

## 15 Regulatory information

- **Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):**

The product is classified and labelled according to GHS-regulations.

- **Hazard symbols:** GHS08
- **Signal word:** Danger
- **H-Phrases:**

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• **P-Phrases:**

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• **National regulations (Germany):**

• **Water hazard class:** see chapter 12

• **Storage class TRGS 510:** 6.1C

## 16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

• **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.