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

· **Informations to product No. 5230**

· **Product name:**

Estriol, mikronisiert, API (mikrobielle Herkunft)
Estriolum

· **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:**

H351 Suspected of causing cancer

H360 May damage fertility or the unborn child


· **P-Phrases:**

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

P281 Use personal protective equipment as required

Carc. 2

Repr. 1A

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2 Composition / information on ingredients

- **Chemical characterization:**

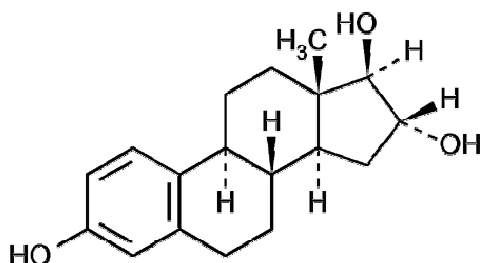
CAS-No. Substance name:

50-27-1 Estriol

- **EINECS-No.:** 200-022-2

- **REACH Reg. No.:** (pre-registered)

- **INCI-Name:** -



4 First aid measures


- **After inhalation:** Fresh air. If irritation of respiratory ways continues, 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. Call in ophthalmologist.
- **After swallowing:** Drink water. Induce vomiting. Seek medical advice.
- **Additional information:** The following symptoms might occur: Drop in blood pressure, vomiting.

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 but not flammable. In case of fire dangerous gases / vapours can be released: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Prevent fire extinguishing water from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.

6 Accidental release measures

- **Personal protective measures:** Avoid dust formation and contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

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7 Handling and storage

- **Handling:**
- **Informations to fire or explosion protection:** No special requirements.
- **Storage:**
- **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. Vapours or Avoid inhalation of dust. Avoid contact with eyes and skin.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of Latex or PVC
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 284 - 285 °C
- **Boiling point / boiling range:** not determined
- **Explosion hazard:** The product is not explosive, but explosive dust-air-mixtures can be formed.
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** not soluble
- **pH-range:** neutral

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Hazardous reactions:** Reactions with strong oxidants and acids.
- **Hazardous decomposition products:** In case of fire: Carbon monoxide und Carbon dioxide

11 Toxicological information

- **Acute toxicity:**
LD50 rat: > 4000 mg/kg
LD50 mus: > 4000 mg/kg
LD50 s.c. rat > 4000 mg/kg

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LD50 s.c. mus: > 4000 mg/kg

LD50 i.p. rat: > 4000 mg/kg

LD50 i.p. mus: > 4000 mg/kg

NOEL 3 mg/kg

• **Primary irritant effect:** Not irritant.

• **Sub-acute / chronic toxicity:** There are sufficient signs that the product can impair human fertility. In animal experiments this properties were proved. The evaluation of a teratogene effect is not yet complete. If this substance is consumed by breast-feeding women it can impair lactation or migrate into the milk and possibly damage the health of the child.

12 Ecological information

• **Ecotoxicological effects:**

Quantitative ecotoxicological data for this product are not available.

• **Additional information:**

Prevent from entering into environmental waters, waste water or soil! Danger to drinking water if even small quantities leak into the ground.

• **Water hazard class:** 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:**

H351 Suspected of causing cancer

H360 May damage fertility or the unborn child

• **P-Phrases:**


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

P281 Use personal protective equipment as required

• **National regulations (Germany):**

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

• **Storage class TRGS 510:** 6.1C

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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.