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

· **Informations to product No. 5232**

· **Product name:**

Estradiolvalerat, API (mikrobielle Herkunft)
Estradioli valeras

· **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.

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3 Composition / information on ingredients

CAS-No. Substance name

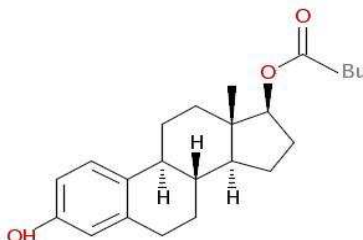
979-32-8 Estradiol valerate

• **EINECS-No.:** 213-559-2

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

• **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.

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7 Handling and storage

- **Handling:** Avoid contact with skin, eyes and clothing. Product to be handled only under local exhaust ventilation. For processing in form of fine crystals take measures for dust explosion protection.
- Information for safe handling: Ensure good ventilation / exhaustion at the workplace.
- **Storage:**
- **Requirements for storage areas and containers:**
Sealed. Dry. Protect from light. At room temperature (+15 ° C to +25 ° C).
- **Advices on common storage:** Not required
- **Additional informations to storage conditions:** None

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:** 143 - 150 °C (Decomposition)
- **Boiling point / boiling range:** not determined
- **Flash point:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** (20 °C, pH 5 – 9) < 0,33 mg/l

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.

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11 Toxicological information

• Acute Toxicity

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

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

• Primary irritation:

• on skin: no data available

• on eyes: no data available

• Sensitization: none sensitizing effect known

• Carcinogenicity All steroid hormones can stimulate the growth of hormone-dependent tissues and tumors.

• Reproduction toxicity:

TDL ₀	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)
TDL ₀ / 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))
TD _{low}	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])
TDL ₀	0,008 mg/kg (mouse) (Female (3-4 d. after conception))

12 Ecological information

• Ecotoxicological effects:

EC50 (Daphnia magna): >100mg/l

EC50(Algen): >100mg/l

• Additional information: Prevent from entering into environmental waters, waste water or soil!

• log Pow: 5,93

• 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.

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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:**

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

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P281 Use personal protective equipment as required

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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.