



Safety data sheet according to 1907/2006/EC, Article 31

Printing date 13.09.2021

Version number 1.00

Revision: 13.09.2021

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

- **Product identifier**
- **Trade name:** Estriol, micronized, API (microbial origin)
- **Article number:** 5230
- **CAS Number:**
50-27-1
- **EC number:**
200-022-2
- **Registration number** The substance is exempt from REACH-registration.
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
- **Uses advised against** No relevant information available.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY
- **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
- **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Carc. 2 H351 Suspected of causing cancer.
Repr. 1A H360 May damage fertility or the unborn child.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



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- **Signal word** Danger
- **Hazard statements**
 - H351 Suspected of causing cancer.
 - H360 May damage fertility or the unborn child.
- **Precautionary statements**
 - P201 Obtain special instructions before use.
 - P202 Do not handle until all safety precautions have been read and understood.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 - P308+P313 IF exposed or concerned: Get medical advice/attention.
 - P405 Store locked up.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterisation: Substances**
- **CAS No. Description**
 - 50-27-1 Oestriol
- **Identification number(s)**
- **EC number:** 200-022-2

4 First aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
 - All regular extinguishing media can be used.
 - Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**
 - Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- **Advice for firefighters**
- **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.

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· Additional information

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Avoid contact with the substance.

· Environmental precautions: Do not allow to enter sewers/ surface or ground water.**· Methods and material for containment and cleaning up:**

Take up dry. Clean up with water.

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.

7 Handling and storage

· Handling:**· Precautions for safe handling** No special precautions are necessary if used correctly.**· Information about fire - and explosion protection:** No special measures required.**· Conditions for safe storage, including any incompatibilities****· Storage:****· Requirements to be met by storerooms and receptacles:**

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

· Information about storage in one common storage facility: Not required.**· Further information about storage conditions:** No further information**· Storage class:** TRHS 510: 6.1 C Combustible acutely toxic or chronic substances**· Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical facilities: No further data; see item 7.**· Control parameters****· Ingredients with limit values that require monitoring at the workplace:** Not required.**· Exposure controls****· Personal protective equipment:****· General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· Respiratory protection: Dust protection mask.**· Protection of hands:** Protective gloves**· Material of gloves**

PVC gloves

Natural rubber, NR

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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:** Solid**Colour:** White**· Odour:** Odourless**· Odour threshold:** Not determined.**· pH-value:** Not applicable.**· Change in condition****Melting point/freezing point:** 284–285 °C**Initial boiling point and boiling range:** Undetermined.**· Flash point:** Not applicable.**· Flammability (solid, gas):** Product is not flammable.**· Decomposition temperature:** Not determined.**· Auto-ignition temperature:** Not determined.**· Explosive properties:** Product does not present an explosion hazard.**· Explosion limits:****Lower:** Not determined.**Upper:** Not determined.**· Vapour pressure:** Not applicable.**· Density at 20 °C:** 0.956 g/cm³**· Relative density** Not determined.**· Vapour density** Not applicable.**· Evaporation rate** Not applicable.**· Solubility in / Miscibility with****water:** Not determined.**· Partition coefficient: n-octanol/water:** Not determined.**· Viscosity:****Dynamic:** Not applicable.**Kinematic:** Not applicable.

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- **Other information** No further relevant information available.
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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 oxidising agents.
Reacts with strong acids.
 - **Conditions to avoid** No further relevant information available.
 - **Incompatible materials:** No further relevant information available.
 - **Hazardous decomposition products:** Carbon monoxide and carbon dioxide
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11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
 - **Additional toxicological information:**
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity**
Suspected of causing cancer.
 - **Reproductive toxicity**
May damage fertility or the unborn child.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.
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12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
 - **Persistence and degradability** No further relevant information available.
 - **Behaviour in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
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- **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 together with household garbage. Do not allow product to reach sewage system.
 - **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to local regulations.
-

14 Transport information

- **UN-Number** Not subject to transport regulations.
 - **ADR, IMDG, IATA** not regulated
 - **UN proper shipping name**
 - **ADR, IMDG, IATA** not regulated
 - **Transport hazard class(es)**
 - **ADR, ADN, IMDG, IATA**
 - **Class** not regulated
 - **Packing group**
 - **ADR, IMDG, IATA** not regulated
 - **Environmental hazards:** Not applicable.
 - **Special precautions for user** Not applicable.
 - **Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.
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15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed
 - **National regulations:**
 - **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
 - **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.
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16 Other information

- The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.
- **Reasons for alterations** This version replaces all old versions.
 - **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association

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GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Carc. 2: Carcinogenicity – Category 2

Repr. 1A: Reproductive toxicity – Category 1A

GB