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

· **Informations to product No. 4555**

· **Product name:**

Progesteron, mikronisiert, API, synth.
Progesteronum

· **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

P280 Wear protective gloves/protective clothing/eye protection/face protection

Carc. 2


Repr. 1A

3 Composition / information on ingredients

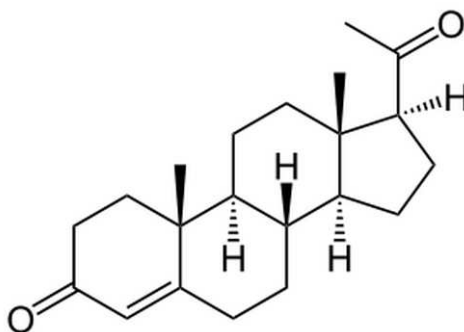
CAS-No. Substance name

57-83-0 Progesteron

· **EINECS-No.:** 200-350-6

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- **REACH Reg. No.:** 01-2119457576-27-0000
- **INCI-Name:** -
- **Chemical characterization:**



4 First aid measures

- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately. Show product-label or this MSDS.
- **after skin contact:** Wash away with plenty of water.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **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 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 contact with substance.
- **Environmental protective measures:** Prevent from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.
- **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:**
- **Requirements for storage areas and containers:**
Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

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- **Additional informations to storage conditions:** none

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:**
Keep away from food, beverages and animal food.
Take off contaminated clothes immediately.
Wash hands before breaks and after work.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber
- **Eye protection:** Safety glasses

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** Odourless
- **Melting point / melting range:** 129 - 130 °C
- **Boiling point / boiling range:** not determined
- **Flammability (solid, vapours):** The product is not flammable.
- **Explosion hazard:** The product is not hazardous for explosion, but the explosion of dust-air mixtures is possible.
- **Density:** (20 °C) 1,166 g/cm³
- **Solubility in / Miscibility with**
- **Water:** not soluble
- **Additional information:** Readily soluble in Chloroform.

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**
No decomposition during appropriate use.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** none

11 Toxicological information

- **Acute toxicity:**
LD50 oral, rat: >5000 mg/kg
- **Other information (experimental toxicology):**
Under physiological conditions in living tissue occurring substance.
Therapeutically used, physiologically highly active substance.
- **Sub-acute / chronic toxicity:**
Based on obvious evidence from animal experiments a risk of teratogenity must be considered as likely. Pregnant women should not be exposed to the product. There are certified evidences for a correlation between substance contact and damage of fertility for man.
- **Additional toxicological informations:**
After long termed exposure:

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Disorder of gastrointestinal tract and liver. Disorder of electrolyt balance. Possible symptoms: Allergic reactions, lack of appetite, stomach cramps.

12 Ecological information

Aquatic toxicity:

Not acute harmful for water organisms.

- **Water hazard class (german regulation):** 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
P280 Wear protective gloves/protective clothing/eye protection/face protection
- **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