

<p>Page 1 of 5</p> <p>Print Date 21.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Clobetasolpropionat, mikronisiert, API</p>	 <p>Revision Date 21.11.2018</p>
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## 1 Identification of the substance/mixture and of the company/undertaking

· **Informations to product No. 5188**

· **Product name:**

**Clobetasolpropionat, mikronisiert, API**  
Clobetasoli propionas

· **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

H373 May cause damage to organs through prolonged or repeated exposure

H413 May cause long lasting harmful effects to aquatic life

· **P-Phrases:**

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


P281 Use personal protective equipment as required

P273 Avoid release to the environment

**Repr. 1B**

**STOT RE 2**

**Aquatic Chronic 4**

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### 3 Composition / information on ingredients

**CAS-No. Substance name**

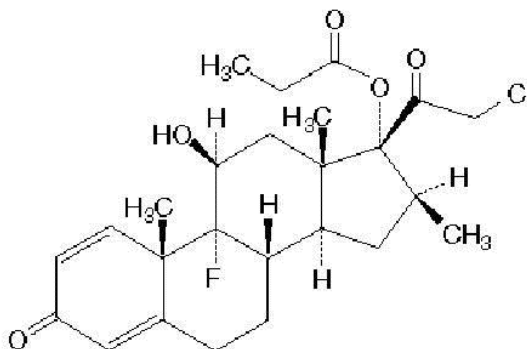
25122-46-7 Clobetasol-17-propionat

• **EINECS-No.:** 246-634-3

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

• **INCI-Name:** -

• **Chemical characterization:**



### 4 First aid measures


- **after inhalation:** Fresh air or oxygen. If feeling unwell continuously seek medical advice.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap, if irritation continues, seek medical advice.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open. If irritation continues, call in ophthalmologist.
- **after swallowing:** If feeling unwell continuously 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, organic halogen compounds.
- **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:** No special requirements.
- **Advice on safe handling:** Good exhaustion / ventilation of working place.
- **Informations to fire or explosion protection:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature ( +15°C to +25°C ). Protect from light.
- **Additional informations to storage conditions:** Keep container tightly closed.

## 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.  
Avoid contact with eyes and skin.
- **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:** 190 - 200 °C
- **Flash point:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** not soluble

## 10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**  
No decomposition during appropriate use.
- **Materials to avoid:** Strong oxidants and bases.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** harmful gases in case of fire.

## 11 Toxicological information

- **Acute toxicity:**  
**LD/LD50-data relevant for hazard classification:**  
LD50 (oral,Rat): > 3000 mg/kg  
LD50 (i.p.,Rat): 351 mg/kg

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LD50 (s.c., Rat): 366 mg/kg  
LD50 (oral, Mouse): > 3000 mg/kg  
LD50 (i.p., Mouse): 118 mg/kg  
LD50 (s.c., Mouse): 81,7 mg/kg

- **Primary irritant effect:**
- **on skin:** Irritant effect
- **on eyes:** Irritant effect.

## 12 Ecological information

- **Ecotoxicological effects:**  
EC50 (Fish): 0,75 mg/l/96h  
Not readily biodegradable.
- **Log pOW:** 2,48
- **Water hazard class:** 2 (self classification): hazardous for water.
- **General remarks:** Do not allow to enter surface and ground water, waste water or soil.

## 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, GHS07  
H360 May damage fertility or the unborn child  
H373 May cause damage to organs through prolonged or repeated exposure  
H413 May cause long lasting harmful effects to aquatic life
- **P-Phrases:**  
P202 Do not handle until all safety precautions have been read and understood  
P281 Use personal protective equipment as required  
P273 Avoid release to the environment
- **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.