


<p>Page 1 of 4</p> <p>Print Date 28.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Fluocinolonacetonid, mikronisiert, API</p>	 <p>Revision Date 28.11.2018</p>
-------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------

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

· **Informations to product No. 5235**

· **Product name:**

**Fluocinolonacetonid, mikronisiert, API**  
Fluocinolon acetonide, micronized

· **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:** Warning

· **H-Phrases:**

H361 Suspected of damaging 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

Repr. 2


## 3 Composition / information on ingredients

**CAS-No. Substance name**

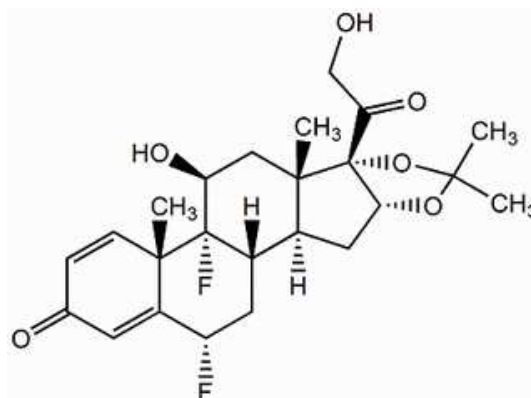
67-73-2 Fluocinolonacetonid

· **EINECS-No.:** 200-668-5

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

<p>Page 2 of 4</p> <p>Print Date 28.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Fluocinolonacetonid, mikronisiert, API</p>	 <p>Revision Date 28.11.2018</p>
-------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------

- **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:** 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 plenty of water. Induce vomiting. Seek medical advice immediately.

#### 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 vapours/gases can be generated: Smoke gases, fluorine 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:** Wear protective equipment.
- **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.

#### 7 Handling and storage

- **Handling:**
- **Advice on safe handling:** Wear protective equipment. Good ventilation / exhaustion of working

<p>Page 3 of 4</p> <p>Print Date 28.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Fluocinolonacetonid, mikronisiert, API</p>	 <p>Revision Date 28.11.2018</p>
-------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------

place. Avoid dust formation.

- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store cool and dry. Protect from light.
- **Advices on common storage:** Not required.

## 8 Exposure controls / personal protective equipment

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

## 9 Physical and chemical properties


- **Form:** crystalline powder
- **Colour:** white
- **Odour:** nearly odourless
- **Melting point / melting range:** 267 – 269 °C
- **Boiling point / boiling range:** not determined
- **Solubility in / Miscibility with**
- **Water:** nearly not soluble.
- **pH-range:** not determined.

## 10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**  
No decomposition if used appropriately.
- **Hazardous reactions:** Reactions with strong oxidants.
- **Hazardous decomposition products:** In case of fire: Fluorine compounds.

## 11 Toxicological information

- **Acute toxicity:**  
**LD/LD50-data relevant for hazard classification:**  
**LD50: (oral, Rat):** > 4000 mg/kg
- **Primary irritating effect:**
- **on skin:** Irritant on skin and mucous membrans
- **on eyes:** Irritant
- **Additional toxicological informations:** Suspected of causing teratogene effects.

<p>Page 4 of 4</p> <p>Print Date 28.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Fluocinolonacetomid, mikronisiert, API</p>	 <p>Revision Date 28.11.2018</p>
-------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------

## 12 Ecological information

- **Ecotoxical effects:**

Quantitative data about ecological effects of this product are not available.

- **General advices:** Prevent from leaking into ground water, environment waters or drainage.
- **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:** Warning

- **H-Phrases:**

H361 Suspected of damaging 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.