


Page 1 of 5 Print Date 03.12.2018	Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Hydrocortisonacetat, mikronisiert, API	 Revision Date 03.12.2018
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1 Identification of the substance/mixture and of the company/undertaking

· **Informations to product No. 2272**

· **Product name:**

Hydrocortisonacetat, mikronisiert, API Hydrocortisoni acetat (mikrobielle Herkunft)

· **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:**

H361 Suspected of damaging fertility or the unborn child

· **P-Phrases:**


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

P308 IF exposed or concerned:

P313 Get medical advice/ attention.

P281 Use personal protective equipment as required.

Repr. 2

<p>Page 2 of 5</p> <p>Print Date 03.12.2018</p>	<p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Hydrocortisonacetat, mikronisiert, API</p>	 <p>Revision Date 03.12.2018</p>
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3 Composition / information on ingredients

CAS-No. Substance name

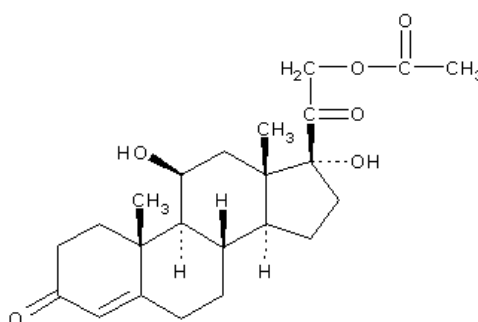
50-03-3 Hydrocortisone acetate

• **EINECS-No.:** 200-004-4

• **REACH Reg. No.:** 01-2119463276-35-0001

• **INCI-Name:** -

• **Chemical characterization:**



4 First aid measures


- **after inhalation:** Bring the person out of the contaminated area to fresh air, assure medical help immediately. Show product-label or this MSDS.
- **after skin contact:** Take off contaminated clothes and shoes, wash away from skin immediately with water and soap, seek medical advice immediately, even if no immediate symptoms are observed.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open. Call in ophtalmologist.
- **after swallowing:** Drink water. Induce vomiting. Seek medical advice.
- **Medical advice:** The half-life period of hydrocortisone in plasma is about 30 minutes. The half-life period of hydrocortisone in tissue, which determines the duration of the biological effect, is about 8-12 hours.

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.
- **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:** Good ventilation of working place. Avoid inhalation of dust. Avoid contact with substance. Do not smoke. Protective equipment: Protection gloves of Latex or PVC
- **Environmental protective measures:** Prevent substance from entering into drainage ditch, surface

Page 3 of 5 Print Date 03.12.2018	Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Hydrocortisonacetat, mikronisiert, API	 Revision Date 03.12.2018
--	--	---

waters, ground water and flowing waters.

- **Methods for cleaning:** Take up dry. Avoid contact with substance.

7 Handling and storage

- **Handling:**
- **Informations to fire or explosion protection:** 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).
- **Additional informations to storage conditions:** Keep container tightly closed. Protect from light.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:**
Wash hands before breaks and after work. Avoid inhalation of dust. Avoid contact with eyes and skin.
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of latex or PVC
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 221 - 224 °C
- **Flash point:** not determined
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** not soluble
- **pH-range:** (10 g/l Suspension) 5,5 - 7,5

10 Stability and reactivity

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

11 Toxicological information

- **Acute toxicity:**
LD50 (i.p., Mouse): 2300 mg/kg
- **LD/LD50-data relevant for hazard classification:**
Oral: LD50: > 5000 mg/kg (rat)
- **Primary irritant effect:**
Eye irritation (Rabbit): in the beginning slight eye irritation, which is not detectable after 24 or 48

Page 4 of 5 Print Date 03.12.2018	Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Hydrocortisonacetat, mikronisiert, API	 Revision Date 03.12.2018
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hours.

• **Other information (experimental toxicology):**

Gen toxicity: Ames-Test and primary liver parenchyme-USD-test: negative.

Teratogenity: In animal experiments corticosteroides are regulary teratogenous. There are no well controlled studies for the application for women. The application by pregnant women can not be considered as safe. Cancerogenity: Cancerogenity tests in vivo: negative. Not listed as cancerogene in IARC, NTP or OSHA.

12 Ecological information

- **Aquatic toxicity:** Quantitative ecotoxicological data for this product are not available.
- **log p(O/W):** 3,81
- **Water hazard class:** 1 (self classification): hazardous for water.

13 Disposal considerations

- **Product:**
- **Recommendation:** Disposal according to local regulations as pharmaceutical waste or organic laboratory chemicals.
- **Empty contaminated packaging:**
- **Recommendation:** Disposal according to the local regulations.

14 Transport informations

- **Land transport ADR/RID and GGVS/GGVE:**
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:**

H361 Suspected of damaging fertility or the unborn child

- **P-Phrases:**

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

P308 IF exposed or concerned:


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- **National regulations (Germany):**

- **Water hazard class:** see chapter 12

- **Storage class TRGS 510:** 6.1C

Page 5 of 5 Print Date 03.12.2018	Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Hydrocortisonacetat, mikronisiert, API	 Revision Date 03.12.2018
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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.