

<p>Page 1 of 5</p> <p>Print Date 22.11.2018</p>	<p>Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Hydrocortison, mikronisiert, API (mikrobielle Herkunft)</p>	 <p>Revision Date 22.11.2018</p>
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1 Identification of the substance/mixture and of the company/undertaking

· **Informations to product No. 2270**

· **Product name:**

Hydrocortison, mikronisiert, API (mikrobielle Herkunft)
Hydrocortisonum

· **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

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3 Composition / information on ingredients

CAS-No. Substance name

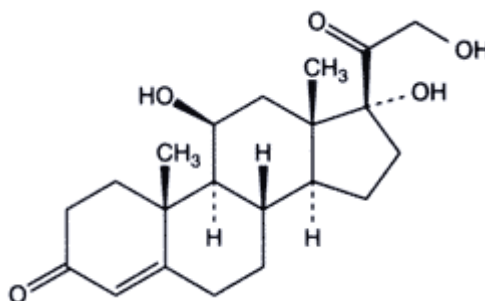
50-23-7 Cortisol

• **EINECS-No.:** 200-020-1

• **REACH Reg. No.:** 01-2119455546-32-0002

• **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 clothings 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:**

Avoid contact with substance and dust formation.

- **Environmental protective measures:** Prevent from entering into drains.

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• **Methods for cleaning:**

Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

7 Handling and storage

• **Storage:**

• **Requirements for storage areas and containers:**

Keep container tightly closed. Cool and dry. Protect from light.

8 Exposure controls / personal protective equipment

• **Personal protective equipment:**

• **Respiratory protection:** Dust protection mask.

• **Hand protection:** Protection gloves of rubber or latex.

• **Eye protection:** Safety glasses.

9 Physical and chemical properties

• **Form:** solid

• **Colour:** white

• **Odour:** odourless

• **Melting point / melting range:** ca. 215 °C

• **Flash point:** not determined

• **Density:** not determined

• **Solubility in / Miscibility with**

Solvent (25°C)

Water 0,28 g/l

Ethanol 15 g/l

Methanol 6,2 g/l

Acetone 9,3 g/l

Chloroform 1,6 g/l

DMF readily soluble

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): 150 mg/kg

LD50 (s.c., Rat): 449 mg/kg

LD/LD50-data relevant for hazard classification:

50-23-7 Hydrocortisone

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Oral: LD50: > 5000 mg/kg (rat)

• **Spezifisches Symptome im Tierversuch:**

Eye irritation (Rabbit): in the beginning slight eye irritation, which is not detectable after 24 or 48 hours.

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

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

Teratogenicity: In animal experiments corticosteroids are regularly teratogenic. There are no well controlled studies for the application for women. The application by pregnant women can not be considered as safe. Cancerogenicity: Cancerogenicity tests in vivo: negative. Not listed as carcinogen in IARC, NTP or OSHA.

12 Ecological information

- **Aquatic toxicity:** Quantitative ecotoxicological data for this product are not available.
- **log p(O/W):** 3,7
- **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 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

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- **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.