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

· **Informations to product No. 2550**

· **Product name:**

Prednisolon, mikronisiert, API (mikrobielle Herkunft)
Prednisolonum

· **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:**

H360D May damage 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. 1B

3 Composition / information on ingredients

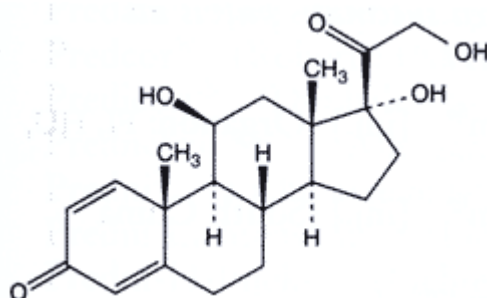
· **Chemical characterization:**

CAS-No. Substance name

50-24-8 Prednisolon

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- **Identification number(s)**
- **EINECS-No.:** 200-021-7
- **REACH Reg. No.:** 01-2119560581-40-0000
- **INCI-Name:** -



4 First aid measures

- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately.
- **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.
- **after swallowing:** Seek medical help 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.
- **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 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.

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- **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:** 218 °C (under nitrogen)
- **Boiling point / boiling range:** not determined
- **Flammability (solid, vapours):** The product is not flammable.
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** Not soluble
- **Additional information:** In Methanol and dioxane soluble, in acetone, ethanol and chloroform moderately soluble.

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:**
Acute effect after exposition: raise in blood pressure, disorder of electrolyte balance because of sodium/liquid retention and raised waste of potassium.
- **LD/LD50-data relevant for hazard classification:**
 - i.v. 120 mg/kg rat
 - i.v. 180 mg/kg mou
 - i.p. 2000 mg/kg rat
 - i.p. 929 mg/kg mou
 - oral 1680 mg/kg mou
 - oral > 500 mg/kg mou
 - s.c. > 240 mg/kg rat

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s.c. 3500 mg/kg mou

• **Primary irritating effect:**

- **on skin:** Not irritant
- **on eyes:** Not irritant

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

Effect of exaggerated chronic exposure: Functional repression of hypophysis and adrenal gland including liquid retention and disorder in electrolyte balance, Cushing - syndrome, hyperglycaemia and glycosuria, raised susceptibility for infections due to repression of immune reaction, generation of ulcers in gastrointestinal tract (bleedings/perforations), osteoporosis, weakness in arms and legs, a cataract and glaucoma with possible damage of nervus opticus, nervousness with sleep disturbances and rapid change of mood, acne and menstruation disorders. The effects are magnified after longer exposure of weeks or months.

• **Sub-acute / chronic toxicity:**

In animal experiments a teratogenic effect was observed. Though no sufficient reproductive studies with men were proceeded, after consumption of high doses by pregnant women no visible effect on the developing fetus was observed. This is possibly due to a lack of corresponding receptors in the human organism or to the capability of the placenta to oxidize prednisolone to less active corticosteroids.

12 Ecological information

• **Information about elimination (persistence and degradability):**

Biodegradation: > 95 %, readily biodegradable (15-day-experiment, Hoechst)

• **log p(O/W):** 1,62

• **Aquatic toxicity:**

Fish toxicity: LC50 (leuciscus idus) > 500 mg/l

Bacteria toxicity: EC50 (bacteria) 2000 mg/l

• **General advices:** Prevent from entering sewage water or drainage ditch undiluted or unneutralized.

• **Water hazard class:** 2 (VwVwS): 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

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• **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.