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

· **Informations to product No. 2211**

· **Product name:**

Dexamethasonum, mikronisiert, API
Dexamethasonum

· **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

P281 Use personal protective equipment as required

Repr. 2

3 Composition / information on ingredients


CAS-No. Substance name

50-02-2 Dexamethason

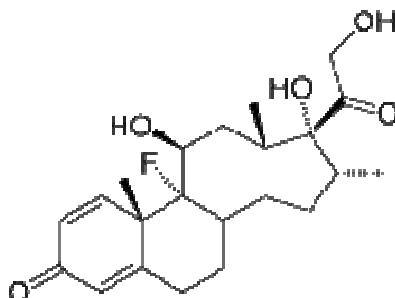
· **EINECS-No.:** 200-003-9

· **REACH Reg. No.:** 01-2120746369-43-0000

· **INCI-Name:** -

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• **Chemical characterization:**



4 First aid measures

- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately.
- **after skin contact:** Wash away with water and soap. If skin irritations are observed seek medical advice.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** Drink water. Induce vomiting. 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.
- **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.
- **Environmental protective measures:** Avoid entering into drains, prevent from contaminating surface water or the ground water system.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water. Avoid dust formation.

7 Handling and storage

- **Handling:**
- **Advice on safe handling:** Wear respiratory protection. If dusts are generated good ventilation/exhaustion of working place required. Avoid generating dusts.
- **Informations to fire or explosion protection:** Take measures to prevent electrostatic charging. Dust can form explosive mixtures with air.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room

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temperature (+15°C to +25°C).

- **Advices on common storage:** Do not store together with strong oxidants
- **Additional informations to storage conditions:**
Keep container tightly closed, store at a good ventilated place.

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:** powder
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 250 – 253 °C
- **Boiling point / boiling range:** Not determined.
- **Explosion hazard:** Dust explosion hazard during handling of big quantities: 198 bar m/s
- **Density:** Not determined.
- **Solubility in / Miscibility with**
- **Water:** nearly not soluble.

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**
Avoid strong heating. Thermal decomposition at 220 °C.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** None.

11 Toxicological information

- **Acute toxicity:**
LD50 (oral, rat): > 3000 mg/kg
LD50 (i.p., rat): 54 mg/kg
- **Primary irritant effect:**
- **on skin:** Slight irritation.
- **in eyes:** Slight irritation.
- **Sensitization:** Not sensitizing
- **Other information (experimental toxicology):** May have some genotoxic effects (by analogy).
- **Sub-acute / chronic toxicity:** In animals, experiments have shown teratogenic effects, various with species. Anti-inflammatory corticoid.
Bodyweight gain, acne, purpura, excitation and sleep disorders, metabolic and endocrinal disorders (cf corticoid).

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12 Ecological information

- **Aquatic toxicity:** Quantitative data about ecological effects of this product are not available, but the high physiological activity indicates harmful properties in environmental waters.
- **log p(O/W):** 2,93
- **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
H373: May cause damage to organs through prolonged or repeated exposure.
- **P-Phrases:**
P202 Do not handle until all safety precautions have been read and understood
P281 Use personal protective equipment as required
P309 IF exposed or if you feel unwell:
P311 Call a POISON CENTER or doctor/ physician.
- **National regulations (Germany):**
- **Water hazard class:** see chapter 12
- **Storage class TRGS 510:** 11

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.