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

- **Informations to product No. 5580**
- **Product name:**

Spironolacton, mikronisiert, API
Spironolactonum

- **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:**

H360 May damage 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. 1B

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3 Composition / information on ingredients

• **Chemical characterization:**

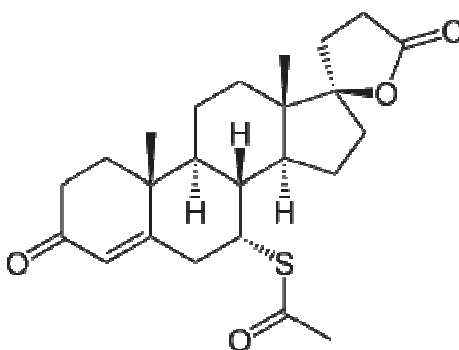
CAS-No. Substance name

52-01-7 Spironolacton

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

• **INCI-Name:** -

• **EINECS-No.:** 200-133-6



4 First aid measures


- **after inhalation:** Fresh air or oxygen. If feeling unwell continuously seek medical advice.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap. If irritation continues seek medical advice immediately.
- **After eye contact:** Rinse out with plenty of water with the eyelid wide open. Call in ophthalmologist.
- **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.
- **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.

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7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Ensure good ventilation / exhaustion at the workplace. Avoid formation of dust. Dust / smoke / mist not breathe, protect from heat, sparks and open flames. Avoid contact with skin and eyes. Put on breathing apparatus. Work only in fume cupboard.

- **Informations to fire or explosion protection:** Protect from heat. Eliminate all sources of ignition. In empty containers may form explosive mixtures. Containers and handling equipment must be grounded to prevent electrostatic charging. The product is combustible

- **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-light yellow

- **Odour:** characteristic (faint mercaptane-like odour)

- **Decomposition temperature:** 201 °C

- **Melting point / melting range:** 207 - 208 °C

- **Boiling point / boiling range:** not determined.

- **Explosion hazard:** The product is not explosive, but explosive dust-air-mixtures can be formed.

- **Density:** not determined

- **Solubility in / Miscibility with**

- **Water:** (25 °C) 0,022 g/l


- **pH-range:** neutral

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.

- **Hazardous reactions:** Reactions with strong oxidants and acids.

- **Hazardous decomposition products:** In case of fire: Carbon monoxide und Carbon dioxide, sulphur oxides.

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11 Toxicological information

- **Acute toxicity:**

- **LD/LD50-data relevant for hazard classification:**

CAS 52-01-7 Spironolacton:

Oral, Rat: LD50: 4121 mg/kg LD50: 1000mg/kg (rat)

- **Primary irritating effect:** not irritant

- **on skin:** hazard by skin contact

- **on eyes:** Irritations.

- **on respiratory organs:** irritations of respiratory organs.

- **if swallowed:** irritations in mouth, throat, esophagus and gastrointestinal tract.

- **Sub-acute / chronic toxicity:**

IARC: Group 3 (not classifiable as to carcinogenicity in humans).

- **Carcinogenicity:** classified as to carcinogenicity in humans

12 Ecological information

- **Aquatic toxicity:**

Quantitative ecotoxicological data are not available.

- **log p(O/W):** 3,56

- **Additional information:** Prevent from entering into environmental waters, waste water or soil.

- **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:** Danger

- **H-Phrases:**

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- **P-Phrases:**

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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.