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

· **Informations to product No. 5090**

· **Product name:**

Budesonid, mikronisiert, API (mikrobielle Herkunft)
Budesonidum

· **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:**

H312 Harmful in contact with skin

H317 May cause an allergic skin reaction

H332 Harmful if inhaled

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

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


P260 Do not breathe dust/fume/gas/mist/vapours/spray

P302 IF ON SKIN

P352 Wash with soap and water

Acute Tox. 4

Skin Sens. 1

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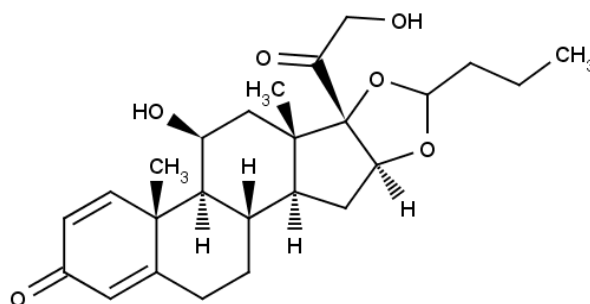
Resp. Sens. 1
Repr. 2

3 Composition / information on ingredients

CAS-No. Substance name

51333-22-3 Budesonid

- **EINECS-No.:** 257-139-7
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -
- **Chemical characterization:**



4 First aid measures


- **after inhalation:** Fresh air, seek medical advice.
- **after skin contact:** Wash away with plenty of water. Remove contaminated clothing.
- **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 but not flammable. In case of fire dangerous gases / vapours can be released: 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 dust formation and contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

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7 Handling and storage

- **Handling:** No special requirements.
- **Advice on safe handling:** Good ventilation / exhaustion of working place.
- **Informations to fire or explosion protection:** Avoid dust formation.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
- **Advices on common storage:** Not required.
- **Additional informations to storage conditions:** Keep container tightly closed.

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.
Avoid contact with eyes and skin.
- **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:** Nearly odourless
- **Melting point / melting range:** 221 - 232 °C
- **Boiling point / boiling range:** not determined
- **Flash point:** not determined
- **Explosion hazard:** Dust explosion possible
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** not readily soluble

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**
No decomposition during appropriate use.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** Irritant or harmful Vapours after thermal decomposition.

11 Toxicological information

- **Acute toxicity:**
LD50(oral, Mouse): 4750 mg/kg
LD50(i.p., Mouse): 179 mg/kg

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12 Ecological information

- **Ecotoxicological effects:**

Quantitative ecotoxicological data for this product are not available.
 Might be harmful for water organisms and plants.

- **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, GHS07

- **Signal word:** Danger

- **H-Phrases:**

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P352 Wash with soap and water

- **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.