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

· **Informations to product No. 5081**

· **Product name:**

Betamethasonvalerat, mikronisiert, API Betamethasoni valeras, Betamethason-17-valerat

· **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:**

H360Df May damage fertility or the unborn child

H372 Causes 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

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Repr. 1B

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3 Composition / information on ingredients

· **Chemical characterization:**

9-fluor-11b,17,21-trihydroxy-16b-methylpregna-1,4-dien-3,20-dion 17-valerat

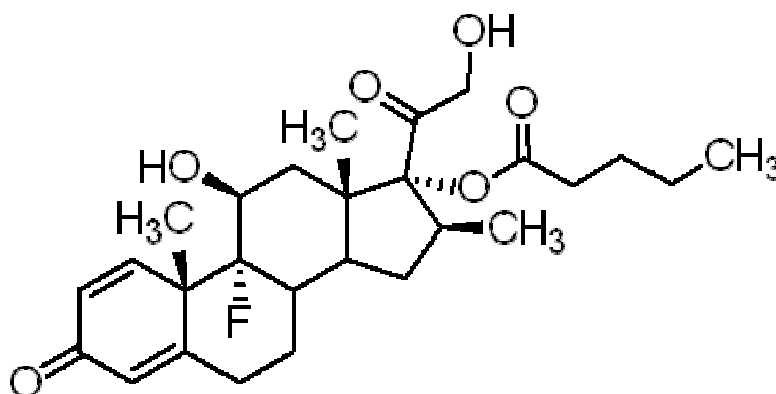
CAS-No. Substance name

2152-44-5 Betamethason-17-valerat

· **EINECS-No.:** 218-439-3

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

· **INCI-Name:** -



4 First aid measures


- **General advices:** Take off contaminated clothes and shoes.
- **after inhalation:** Bring the person out of the contaminated area to fresh air, Seek medical help immediately. Show product-label or this MSDS.
- **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 advice immediately. Show label ort his MSDS..

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, organic fluorine compounds.
- **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:** Prevent from leaking into sewage water, ground water

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system or surface waters. Clean up floor with tenside containing water thoroughly.

· **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

7 Handling and storage

- **Handling:**
- **Advice on safe handling:** If dust is generated provide exhaustion.
- **Informations to fire or explosion protection:** Take measures to prevent electrostatic charging.
- **Storage:**
- **Requirements for storage areas and containers:** Keep container tightly closed and dry. Protect from light. At room temperature (+15 bis +25°C).

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **Respiratory protection:** Dust protection mask.
- **Hand protection:** Protection gloves of rubber.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** ca. 192 °C (Decomposition)
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** 10g/l

10 Stability and reactivity

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

11 Toxicological information

- **Acute toxicity:**
- LD/LD50-data relevant for hazard classification:**
2152-44-5 Betamethason-17-valerat
- LD50 (oral, Rat): > 3000 mg/kg
- LD50 (oral, Mouse): 4067 mg/kg
- LD50 (i.p., Rat): > 4500 mg/kg
- LD50 (scu., Mouse): 496 mg/kg
- LD50 (i.p., Mouse): 632 mg/kg
- LD50 (scu., rabbit): 61,2 mg/kg
- **Other information (experimatal toxicology):**

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Highly active pharmaceutical agent Classification as hazardous substance because of pharmacological systemic steroide effect. Danger of serious health damage after prolonged exposition. Animal experiments revealed a risk of teratogene effect.

12 Ecological information

- **Ecotoxicological effects:** Quantitative data about ecological effects of this product are not available.
- **General notes:** Prevent from entering sewage water or drainage ditch.
- **Water hazard class:** 2 (self classification): hazardous for water.

13 Disposal considerations

- **Product:** 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:**
H360Df May damage fertility or the unborn child
H372 Causes 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
- **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 revision:** Adaption to regulation (EC) 1907/2006 (REACH), 20.05.09