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

• **Informations to product No. 2582**

• **Product name:**

Lactose-Monohydrat Saccharum lactis, Lactosum monohydricum

• **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:**

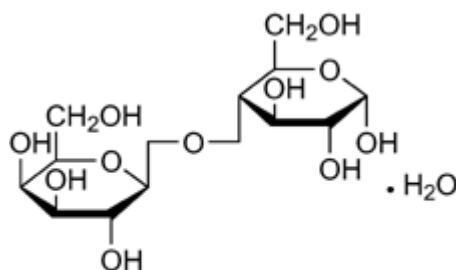
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

2 Hazards identification

• **Hazards identification:** The substance is not classified as dangerous according to European Union legislation.

3 Composition / information on ingredients

• **Chemical characterization:**




CAS-No. Substance name

10039-26-6 Lactose-Monohydrat

• **EINECS-No.:** 200-559-2

• **REACH Reg. No.:** Exempted from the obligation to register according to Annex 4 / 5 REACH-regulation.

• **INCI-Name:** Lactose

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4 First aid measures

- **after eye contact:** Rinse out with plenty of water with the eyelid wide open.
- **after swallowing:** (big quantities): If feeling unwell 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 vapours/gases can be generated: Smoke gases.
- **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

- **Methods for cleaning:** Take up dry. Clean up with water.

7 Handling and storage


- **Handling:** No special requirements.
- **Storage:**
- **Requirements for storage areas and containers:**
Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:** The usual precautions during handling of chemicals are to observe.
- **Respiratory protection:** Not required.
- **Hand protection:** Not required.
- **Eye protection:** Not required.

9 Physical and chemical properties

- **Form:** solid
- **Colour:** white
- **Odour:** odourless.
- **Melting point / melting range:** 223 °C
- **Density:** Bulk density: 500 kg/m³
- **Solubility in / Miscibility with**
- **Water:** readily soluble
- **pH-range:** (50 g/l, 20 °C) 4 - 6

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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:** Naturally occurring substance and food ingredient. In case of appropriate handling and usage the product does not cause harmful effects.

12 Ecological information

- **Aquatic toxicity:**
Quantitative ecotoxicological data for this product are not available.
Not acute harmful for water organisms.
In case of appropriate handling and usage the product does not cause ecological problems.
- **Water hazard class:** 1 (self classification): slightly 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 does not need to be labelled according to GHS-regulations.
- **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.

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· **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.