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

· **Informations to product No. 5730**

· **Product name:**

Placebo Tabletten, oval, weiß

ca. 100 St., 17 x 8 mm

Placebo tablets

· **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:**

Mixture of Cellulose and Lactose

CAS-No. Substance name:

9004-34-6 Cellulose

· **EINECS-No.** 232-674-9

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

· **INCI-Name:** Cellulose


CAS-No. Substance name:

63-42-3 Lactose

· **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 skin contact:** No special measures required
- **After eye contact:** No special measures required.
- **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.

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.

7 Handling and storage


- **Handling:**
- **Advice on safe handling:** Avoid formation of dust. No special measures required.
- **Informations to fire or explosion protection:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:**
Tightly closed. Store at a dry place. At room temperature (+5°C to +25°C).
- **Advices on common storage:** Not required.
- **Additional informations to storage conditions:** Protect from humidity and water.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:** The usual precaution measures during handling of chemicals are to observe.
- **Respiratory protection:** not necessary
- **Hand protection:** Protection gloves of rubber or latex.
- **Eye protection:** not necessary

9 Physical and chemical properties

- **Form:** solid powder.

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- **Colour:** white
- **Odour:** odourless
- **pH-value:** 4.0 – 6.5
- **Melting-point / Melting range:** 202 °C (Lactose)
- **Boiling point:** not determined
- **Flammability:** class 2-3
- **Explosive properties:** Dust explosive
- **Lower explosion limit:** 60 - 125 g/m³
- **Dust explosive class:** ST 1 (Kst. 39 – 72 bar m/s)
- **Max. explosion pressure:** 5,0 – 6,5 bar
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** partially soluble

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition if used according to specifications. Avoid: Moisture and temperatures > 25 ° C.
- **Hazardous reactions:** avoid the formation of dust, potentially explosive
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information


- **Acute toxicity:**
LD/LD50-data relevant for hazard classification:
Oral LD50 > 10g/kg (rat)
- **Primary irritant effect:**
- **on skin:** no irritations
- **on eyes:** no irritations
- **sensitisation:** This product contains trace amounts of milk protein, possible sensitization in allergic patients.
- **Additional toxicological informations:** In case of appropriate handling and usage the product does not cause harmful effects.

12 Ecological information

- **Ecotoxic effects:** In case of appropriate handling and usage the product does not cause ecological problems.
- **Water hazard class:** nwg (self classification): not 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.

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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.

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