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

· **Informations to product No. 4253**

· **Product name:**

Glycerolmonostearat Typ II, 32/36, Kalium Glycerinmonostearat „selbstemulgierend“ Tegin ®

· **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**

85251-77-0 Glycerolmonostearate > 90%

· **EINECS-No.:** 286-490-9

· **REACH Reg. No.:** 01-2119495562-30-0000

· **INCI-Name:** Glyceryl Stearate SE

· **CAS-No. Substance name**

85251-77-0 Potassium stearate < 10%

· **EINECS-No.:** 209-786-1


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

· **INCI-Name:** Potassium Stearate

4 First aid measures

· **after skin contact:** Rinse off with water.

· **after eye contact:** Rinse out with plenty of water with the eyelid wide open.

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- **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 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

- **Environmental protective measures:** Prevent from entering into drainage ditch.
- **Methods for cleaning:**
Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

7 Handling and storage

- **Handling:** Keep away from open fire.
- **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


Components with limit values that require monitoring at the workplace:

The product does not contain relevant quantities of substances with limit values that require monitoring at the workplace.

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

9 Physical and chemical properties

- **Form:** solid
- **Colour:** white-light yellow
- **Odour:** odourless
- **Melting point / melting range:** 54 - 61 °C
- **Boiling point / boiling range:** not determined
- **Flash point:** 190 - 220 °C DIN ISO 2592
- **Density:** (20 °C) 0,92 g/cm³
- **Solubility in / Miscibility with**
- **Water:** emulsant

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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:** At temperatures > 300 °C acrolein can be released.

11 Toxicological information

- **Acute toxicity:** LD50 > 5000 mg/kg oral

• **Additional toxicological informations:** In case of appropriate handling and usage the product does not cause harmful effects.

12 Ecological information

- **Information about elimination (persistence and degradability):** Readily biodegradable.

- **Aquatic toxicity:**

Acute Fish toxicity: LC50 > 100 mg/l

Acute Bacteria toxicity: EC50 > 100 mg/l

- **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

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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.