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

· **Informations to product No. 3438**

· **Product name:**

Softisan ® 378

· **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**

· **Description:** Glycerides of saturated C8 - C18 – fatty acids and unsaturated C18 – fatty acids

CAS-No. Substance name

85536-06-7 Glyceride C8 – C18

· **EINECS-No.:** 287-487-5

· **REACH Reg. No.:** 01-2119964461-36-0000

· **INCI-Name:** Caprylic/Capric/Myristic/Stearic Triglyceride


4 First aid measures

· **after inhalation:** Not relevant

· **after skin contact:** Wash away with water.

· **after eye contact:** If irritations continue, seek medical advice.

· **after swallowing:** If feeling unwell Seek medical advice.

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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

- **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:** No special requirements.
- **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 (+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:**
- **Respiratory protection:** Not required.
- **Hand protection:** Not required.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties

- **Form:** solid
- **Colour:** white – light yellow
- **Odour:** odourless
- **Melting point / melting range:** 39,1 °C
- **Boiling point / boiling range:** > 400 °C
- **Flash point:** not determined
- **Density:** (20 °C) 0,95-0,98 g/cm³
- **Solubility in / Miscibility with**
- **Water:** (20 °C) 2 – 3 mg/l

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10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**

No decomposition during appropriate use.

- **Materials to avoid:** Strong oxidizers

- **Hazardous reactions:** No hazardous reactions known.

- **Hazardous decomposition products:** none

11 Toxicological information

- **Acute toxicity:**

LD50 (oral, rat): > 2000 mg/kg (OECD 401)

LD50 (dermal, rat): > 2000 mg/kg (OECD 402)

- **Primary irritant effect:**

- **on eyes:** Irritant effect possible

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

12 Ecological information

- **Aquatic toxicity:**

Not acute harmful for water organisms.

Nicht akut schädlich für Wasserorganismen.

Bacteria: *Pseudomonas putida* EC50 > 0,8 mg/l/18h

Daphnia: *Daphnia magna* EC50 102,6 mg/l/48h

Algae: *Desdemonus subspicatus* ErC50 13 mg/l/72h

Fish: *Danio rerio* LC50 >10000 mg/l/96h

NOEC (activated sludge) 46,9 mg/l/14d

NOEC (*Desdemonus subspicatus*) 1,19 mg/l/72h

- **Water hazard class:** nwg (VwVwS): 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.

14 Transport informations

- **Land transport according to ADR:**

Not classified as dangerous in the meaning of transport regulations.

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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.