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

• **Informations to product No. 3441**

• **Product name:**

Softisan ® 601

• **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

68439-49-6, 61789-05-7, 84836-98-6 Glycerol-fatty acid-esters, polyethylene glycole, partial glycerides, emulgators

• **EINECS-No.:** 263-027-9, 284-283-8

• **REACH Reg. No.:** -

• **INCI-Name:** Glyceryl Cocoate (and) Hydrogenated Coconut Oil (and) Ceteareth-25

4 First aid measures


• **General advices:** No special measures required.

• **after inhalation:** Not relevant

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

• **after eye contact:** Rinse out with water. If irritations continue, seek medical advice.

• **after swallowing:** Seek medical advice. Do not induce vomiting.

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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

- **Environmental protective measures:** No special measures required.
- **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. General measures for fire- and explosion protection.
- **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:

Polyethylene glycole 600 (PEG 600), respirable fraction.
AGW according to TRGS 900: 1000 mg/ cbm.

- **Personal protective equipment:**
- **Respiratory protection:** Not required.
- **Hand protection:** protection gloves of rubber or latex.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties

- **Form:** Pellets
- **Colour:** yellow
- **Odour:** Characteristic
- **Melting point / melting range:** ca. 42 °C
- **Boiling point / boiling range:** not determined
- **Flash point:** not determined
- **Density:** (20 °C) 0,95 - 0,98 g/cm³
- **Solubility in / Miscibility with**
- **Water:** dispergant

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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, low toxicity.
LD50(dermal,Rat): > 2000 mg/kg, low toxicity.
- **Primary irritant effect:** In animal experiments: Not irritant and not sensitizing.
- **Chronical toxicity:** Ames-Test: not mutagenic.

12 Ecological information

- **Biodegradation:** biodegradable
Fish: Water-soluble concentrations not toxic under test conditions.
Daphnia: Water-soluble concentrations not toxic under test conditions.
Algae: Water-soluble concentrations not toxic under test conditions.
- **Water hazard class:** 2 (VwVwS): 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.