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

· **Informations to product No. 3250**

· **Product name:**

Macrogol-40-Glycerolhydroxystearat ehemals Cremophor® RH 40

· **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.

2 Composition / information on ingredients

· **Chemical characterization:**

CAS-No. Substance name

61788-85-0 Cremophor RH 40 (Hydrated ricinus oil, ethoxylated)

· **EINECS-No.:** 500-147-5

· **REACH Reg. No.:** 01-2120775815-41-0000

INCI-Name: PEG-40 Hydrogenated Castor Oil


4 First aid measures

· **after inhalation:** Not relevant.

· **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.

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

· **after swallowing:** Rinse mouth, drink plenty of water.

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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. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **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 contact with substance.
- **Additional information:** 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:** No special measures required.
- **Informations to fire or explosion protection:** No special measures required.
- **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 precaution measures during handling of chemicals are to observe.
- **Respiratory protection:** Not required.
- **Hand protection:** Protection gloves of rubber or latex.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

- **Form:** paste
- **Colour:** white - light yellow
- **Odour:** nearly odourless
- **Melting point / melting range:** 16 - 26 °C
- **Boiling point / boiling range:** not determined
- **Vapour pressure:** (25 °C) 31,4 hPa
- **Flash point:** 242 °C DIN ISO 2592
- **Ignition temperature:** 375 °C DIN 51794
- **Density:** (60 °C) 1,03 g/cm³ DIN 51757
- **Solubility in / Miscibility with**

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- **Water:** (23 °C) > 490 g/l
- **pH-range:** (100 g/l, 20 °C) 6,0 – 7,0
- **Viscosity:**
- **dynamic:** (60 °C) 176 mPas DIN51562

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** Avoid strong heating. Thermal decomposition above 300 °C.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** none

11 Toxicological information


- **Acute toxicity:**
LD50 (oral,Rat): > 20000 mg/kg
LC50 Rat (inhalativ): > 2,06 mg/l 4 h (OECD 403)
- **Primary irritant effect:**
- **on skin:** Not irritant (OECD 404)
- **on eyes:** Not irritant (BASF-Test)
- **on respiratory organs:** Acute inhalation risk (Rat): no mortality after 8h exposition in atmosphere, saturated at 20°C.

12 Ecological information

- **Information about elimination (persistence and degradability):**
Evaluation biodegradation and elimination (H2O): readily biodegradable (according to OECD-criteria).
Elimination: 80 - 90 % (28 d) (OECD-guideline 301 F) (aerob, activated sludge).
- **Aquatic toxicity:**
Fishes: LC50 (*Oryzias latipes*): > 10000 mg/l/48h (YIK S 0102-1974 ITEM 55, static)
Daphnia: EC50 (48 h) > 100 mg/l, *Daphnia magna* (OECD 202, part 1, static).
Water plants: EC50 (72 h) > 100 mg/l (growth rate), *Desmodium subspicatus* (OECD 201, static)
Bacteria: EC20 (0,5 h) 700 mg/l, activated sludge (OECD 209, aerob)
- **General advices:** Prevent from contaminating surface water, the ground water system or soil.
- **log p(O/W):** (22 °C) - 0,76 Accumulation in organisms is not likely.
- **Water hazard class:** 1 (VwVwS): 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.

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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:** 10

- **VbF class:** -

16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.