


<p>Page 1 of 4</p> <p>Print Date 26.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Macrogol-35-Glycerol-Rizinoleat</p>	 <p>Revision Date 26.11.2018</p>
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## 1 Identification of the substance/mixture and of the company/undertaking

· **Informations to product No. 3262**

· **Product name:**

**Macrogol-35-Glycerolrizinoleat**  
Cremophor® EL Neu: Kolliphor® EL

· **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

· **Hazard classification:** The substance is not classified as dangerous according to European Union legislation.

## 2 Composition / information on ingredients

· **Chemical characterization:**

**CAS-No. Substance name**

61791-12-6 Rizinus oil ethoxylate

· **EINECS-No.:** 500-151-7

· **REACH Reg. No.:** 01-2119958762-26-0000


· **INCI-Name:** PEG-35-Castor Oil

## 4 First aid measures

· **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. Call in ophthalmologist.

· **After swallowing:** Rinse mouth immediately. Drink plenty of water.

<p>Page 2 of 4</p> <p>Print Date 26.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Macrogol-35-Glycerol-Rizinoleat</p>	 <p>Revision Date 26.11.2018</p>
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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.
- **Environmental protective measures:** Prevent from leaking into sewage water, ground water system or surface waters.
- **Methods for cleaning:** Absorb with liquid-binding material: Sand, silica gel, acid binder, universal binder, saw dust. Dispose according to chapter 13 of this MSDS.

## 7 Handling and storage


- **Handling:** No special requirements.
- **Advice on safe handling:** No special measures required.
- **Informations to fire or explosion protection:** No special measures required.
- **Storage:**
- **Requirements for storage areas and containers:** Keep container tightly closed. Kühl und trocken. Store below 25 °C
- **Advices on common storage:** Not required.
- **Additional informations to storage conditions:** none

## 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
- **Eye protection:** Safety glasses

## 9 Physical and chemical properties

- **Form:** liquid
- **Colour:** light yellow
- **Odour:** faint odour
- **Melting point / melting range:** 4 °C
- **Boiling point / boiling range:** > 100 °C
- **Flash point:** 257 °C DIN-ISO 2592
- **Ignition temperature:** 405 °C DIN 51794

<p>Page 3 of 4</p> <p>Print Date 26.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Macrogol-35-Glycerol-Rizinoleat</p>	 <p>Revision Date 26.11.2018</p>
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- **Density:** (25 °C) 1,05-1,06 g/cm<sup>3</sup>
- **Solubility in / Miscibility with**
- **Water** at 20 °C 100 g/l
- **pH-range:** (100 g/l, 20 °C) 6 – 8
- **Viscosity:**
- **dynamic:** (25 °C) 600-800 mPa\*s
- **thermal decomposition:** ca. 300 °C

## 10 Stability and reactivity


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

## 11 Toxicological information

- **Acute toxicity:** After single oral / dermal / inhalative exposition practically not toxic.  
LD50 Rat (oral): > 6.400 mg/kg (BASF-Test)  
Rat (inhalativ): 8 h (IRT)  
Inhalation risk test (IRT): no mortality within 8 hours in animal experiments. Inhalation of saturated atmosphere causes no acute danger.  
LD50 Rat (dermal): > 5.000 mg/kg (BASF-Test)
- **Irritant effect**  
Not irritant on skin and eyes.  
Primary skin irritation Rabbit: Not irritant. (BASF-Test)  
Primary irritations of mucous membranes Rabbit: Not irritant. (BASF-Test)
- **Sensitization**  
No sensitization in animal experiments (guinea pig)
- **Mutagenity**  
No mutagenity observed in several tests on bacteria and mammal cell cultures and mammals.
- **Reproductive toxicity**  
In animal experiments no indication for reproductive toxicity observed.
- **Teratogenity**  
In animal experiments no indication for teratogenity observed.

## 12 Ecological information

- **Ecotoxical effects:**  
Not acute harmful for water organisms. In sewage plants disturbance of the activity of activated sludge is not likely  
Fish toxicity:  
LC50 (48 h) 448 mg/l, Leuciscus idus (DIN 38412 Teil 15, static)  
Aquatic invertebrates:  
EC50 (48 h) > 100 mg/l, Daphnia magna (OECD-Guideline 202, Teil 1, static)  
Water plants:  
EC50 (72 h) > 93 mg/l (growth rate), Desmodemus subspicatus (OECD-Guideline 201, static)  
Micro organisms / Effect on activated sludge:

<p>Page 4 of 4</p> <p>Print Date 26.11.2018</p>	<p><b>Material Safety Data Sheet</b> according to Regulation (EC) No. 1907/2006 (REACH)</p> <p>Macrogol-35-Glycerol-Rizinoleat</p>	 <p>Revision Date 26.11.2018</p>
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EC20 (30 min) > 1.000 mg/l, (DIN EN ISO 8192-OECD 209-88/302/EWG,T. C, aerob)

• **Persistence and degradability:**

Not readily biodegradable. (OECD-criteria). Slow biodegradation.

Elimination: 90 - 100 % DOC-reduction (21 d) (OECD-Guideline 302 B).

• **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:** 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.

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