

## **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name:** Macrogol- 1500 glycerol ricinoleate  
Macrogolglyceroli ricinoleas  
Cremophor® EL Castor Oil
- **Article number:** 100355
- **CAS Number:**  
61791-12-6
- **NLP Number:**  
500-151-7
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## **SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The substance is not classified, according to the CLP regulation.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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## SECTION 3: Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**  
CAS: 61791-12-6 Macrogol- 1500 glycerol ricinoleate  
Macrogolglyceroli ricinoleas  
Cremophor® EL Castor Oil
- **Identification number(s)**
- **NLP Number:** 500-151-7

## SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Fire-extinguishing powder  
Carbon dioxide  
Water spray  
Foam  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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## **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

## **SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:**  
Use suitable respiratory protective device only when aerosol or mist is formed.  
Filter P2
- **Hand protection**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**  
Nitrile rubber, NBR  
Chloroprene rubber, CR  
Butyl rubber, BR  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection** Goggles recommended during refilling
- **Body protection:** Protective work clothing

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**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**General Information**

· Physical state	Fluid
· Colour:	Light yellow
· Odour:	Recognisable
· Odour threshold:	Not determined.
· Melting point/freezing point:	4°C
· Boiling point or initial boiling point and boiling range	>100°C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	257°C
· Decomposition temperature:	Not determined.
· pH	6–8
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic at 20°C:	650–800 mPas
· Solubility	
· water at 20°C:	100 g/l
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.

**9.2 Other information**

· Appearance:	
· Form:	Oily
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.

**Information with regard to physical hazard classes**

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void

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· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

Oral	LD50	>6400 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity:

EC50 (48h)	>100 mg/l (daphnia)
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12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

#### 12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

#### 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

#### 12.7 Other adverse effects

#### Additional ecological information:

#### General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Recommendation Smaller quantities can be disposed of with household waste.

#### Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR, IMDG, IATA not regulated

### 14.2 UN proper shipping name

ADR, IMDG, IATA not regulated

### 14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class not regulated

### 14.4 Packing group

ADR, IMDG, IATA not regulated

### 14.5 Environmental hazards:

Not applicable.

### 14.6 Special precautions for user

Not applicable.

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|---|-----------------|
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | not regulated   |

## SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Directive 2012/18/EU**
  - **Named dangerous substances - ANNEX I** Substance is not listed.
  - **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
Substance is not listed.
  - **REGULATION (EU) 2019/1148**
  - **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**  
Substance is not listed.
  - **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
  - **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
  - **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**  
Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **Date of previous version:** 21.07.2023
- **Version number of previous version:** 1.2
- **Abbreviations and acronyms:**
  - ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
- **\* Data compared to the previous version altered.**

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