according to 1907/2006/EC, Article 31

Printing date 09.08.2023 Revision: 09.08.2023 Version number 1.3 (replaces version 1.2)

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

· 1.1 Product identifier

 Trade name: <u>Macrogol- 1500 glycerol ricinoleate</u> <u>Macrogolglyceroli ricinoleas</u> 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 pharmaceutic 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.

· 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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Trade name: Macrogol- 1500 glycerol ricinoleate Macrogolglyceroli ricinoleas Cremophor® EL Castor Oil

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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.
- No further relevant information avail
- 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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Trade name: Macrogol- 1500 glycerol ricinoleate Macrogolglyceroli ricinoleas Cremophor® EL Castor Oil

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See Section 13 for disposal information.

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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Safety data sheet according to 1907/2006/EC, Article 31

Trade name: Macrogol- 1500 glycerol ricinoleate Macrogolglyceroli ricinoleas Cremophor® EL Castor Oil

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		(Conto. of page
· Flammable solids	Void	
 Self-reactive substances and mixtures 	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
· Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit		
flammable gases in contact with water	Void	
· Oxidising liquids	Void	
Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
· Desensitised explosives	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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Printing date 09.08.2023 Revision: 09.08.2023 Version number 1.3 (replaces version 1.2)

Trade name: Macrogol- 1500 glycerol ricinoleate Macrogolglyceroli ricinoleas Cremophor® EL Castor Oil

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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

EC50 (48h) >100 mg/l (daphnia)

- **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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 • 14.7 Maritime transport in bulk according to IMO instruments
 Not applicable.

 • UN "Model Regulation":
 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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