

Safety data sheet

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BASF Safety data sheet according to UN GHS 4th rev.

Date / Revised: 10.04.2017

Product: **Kolliphor® EL**

Version: 1.2

(ID no. 30554032/SDS_GEN_00/EN)

Date of print 04.08.2017

1. Identification

Product identifier

Kolliphor® EL

Chemical name: Castor oil, ethoxylated

CAS Number: 61791-12-6

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: pharmaceutical excipient

Details of the supplier of the safety data sheet

Company:

BASF SE

67056 Ludwigshafen

GERMANY

Operating Division Nutrition and Health

Telephone: +49 621 60-48434

E-mail address: EN-global-safety-data@basf.com

Emergency telephone number

International emergency number:

Telephone: +49 180 2273-112

2. Hazards Identification

Classification of the substance or mixture

According to UN GHS criteria

Aquatic Acute 3

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For the classifications not written out in full in this section the full text can be found in section 16.

Label elements

Globally Harmonized System (GHS)

Hazard Statement:

H402 Harmful to aquatic life.

Precautionary Statements (Prevention):

P273 Avoid release to the environment.

Precautionary Statements (Disposal):

P501 Dispose of contents/container to hazardous or special waste collection point.

Other hazards

According to UN GHS criteria

High risk of slipping due to leakage/spillage of product. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

3. Composition/Information on Ingredients

Substances

Chemical nature

castor oil, ethoxylated

CAS Number: 61791-12-6

Ph.Eur.: Macroglycerol Ricinoleate 35

For the classifications not written out in full in this section the full text can be found in section 16.

Mixtures

Not applicable

4. First-Aid Measures

Description of first aid measures

Remove contaminated clothing.

If inhaled:

If difficulties occur after vapour/aerosol has been inhaled, remove to fresh air and seek medical attention.

On skin contact:

Wash thoroughly with soap and water.

On contact with eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion:

Rinse mouth and then drink plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms: No significant symptoms are expected due to the non-classification of the product.

Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:

water spray, foam, carbon dioxide, dry powder

Special hazards arising from the substance or mixture

No particular hazards known.

Advice for fire-fighters

Special protective equipment:

Wear a self-contained breathing apparatus.

Further information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Spilled material may cause slippery floors.

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Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Contain with absorbent material (e.g. sand, silica gel, acid binder, general purpose binder, sawdust).

For large amounts: Dike spillage. Vacuum up spilled product. Place into suitable container for disposal.

Dispose of absorbed material in accordance with regulations.

Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

7. Handling and Storage**Precautions for safe handling**

Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Further information on storage conditions: Keep container tightly closed and dry; store in a cool place.

Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

8. Exposure Controls/Personal Protection**Control parameters**

Components with occupational exposure limits

64-19-7: acetic acid...%

Exposure controls

Personal protective equipment

Respiratory protection:

Respiratory protection in case of vapour/aerosol release. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2)

Hand protection:

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Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) etc. Supplementary note: The specifications are based on tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined through testing. Manufacturer's directions for use should be observed because of great diversity of types.

Eye protection:

Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection:

Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Hands and/or face should be washed before breaks and at the end of the shift.

9. Physical and Chemical Properties

Information on basic physical and chemical properties

Form:	oily	
Colour:	light yellow	
Odour:	faint specific odour	
Odour threshold:		
	not determined	
pH value:	6 - 8 (100 g/l, 20 °C)	
Melting point:	approx. 4 °C	
Boiling point:	> 100 °C	
Flash point:	257 °C	(DIN ISO 2592)
Evaporation rate:		
	not determined	
Flammability:	not flammable	
Lower explosion limit:		
	For liquids not relevant for classification and labelling.	
Upper explosion limit:		
	For liquids not relevant for classification and labelling.	
Ignition temperature:	405 °C	(DIN 51794)
Vapour pressure:		
	No data available.	
Density:	1,05 - 1,06 g/cm ³ (25 °C)	

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Relative vapour density (air):
not determined

Solubility in water:
100 g/l
(20 °C)

Solubility (qualitative) solvent(s): organic solvents
soluble

Partitioning coefficient n-octanol/water (log Kow):
not determined

Self ignition: not self-igniting

Thermal decomposition: approx. 300 °C

Viscosity, dynamic: 650 - 800 mPa.s
(25 °C)

Explosion hazard: not explosive

Fire promoting properties: not fire-propagating

Other information

Bulk density:
not relevant

Surface tension:
No data available.

10. Stability and Reactivity

Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals: Corrosive effects to metal are not anticipated.

Chemical stability

The product is chemically stable.

Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

Conditions to avoid

Avoid heat.

Incompatible materials

Substances to avoid:
No substances known that should be avoided.

Hazardous decomposition products

Hazardous decomposition products:

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No hazardous decomposition products if stored and handled as prescribed/indicated.

11. Toxicological Information

Information on toxicological effects

Acute toxicity

Assessment of acute toxicity:

Virtually nontoxic after a single ingestion. Virtually nontoxic after a single skin contact. The inhalation of a highly enriched/saturated vapor-air-mixture represents an unlikely acute hazard.

Experimental/calculated data:

LD50 rat (oral): > 6.400 mg/kg (BASF-Test)

rat (by inhalation): 8 h (IRT)

Inhalation-risk test (IRT): No mortality within 8 hours as shown in animal studies. The inhalation of a highly saturated vapor-air mixture represents no acute hazard.

LD50 rat (dermal): > 5.000 mg/kg (BASF-Test)

Irritation

Assessment of irritating effects:

Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (BASF-Test)

Serious eye damage/irritation rabbit: non-irritant (BASF-Test)

Respiratory/Skin sensitization

Assessment of sensitization:

Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data:

Guinea pig maximization test guinea pig: Non-sensitizing.

Germ cell mutagenicity

Assessment of mutagenicity:

No mutagenic effect was found in various tests with bacteria and mammalian cell culture. The substance was not mutagenic in studies with mammals.

Reproductive toxicity

Assessment of reproduction toxicity:

The results of animal studies gave no indication of a fertility impairing effect.

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Developmental toxicity

Assessment of teratogenicity:

No indications of a developmental toxic / teratogenic effect were seen in animal studies.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

No data available.

Aspiration hazard

No data available.

12. Ecological Information

Toxicity

Assessment of aquatic toxicity:

Harmful to aquatic life.

Acutely harmful for aquatic organisms.

Toxicity to fish:

LC50 (48 h) 448 mg/l, *Leuciscus idus* (DIN 38412 Part 15, static)

The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates:

EC50 (48 h) > 100 mg/l, *Daphnia magna* (OECD Guideline 202, part 1, static)

The details of the toxic effect relate to the nominal concentration.

Aquatic plants:

EC50 (72 h) > 93 mg/l (growth rate), *Desmodesmus subspicatus* (OECD Guideline 201, static)

The statement of the toxic effect relates to the analytically determined concentration.

Microorganisms/Effect on activated sludge:

EC20 (30 min) > 1.000 mg/l, activated sludge, industrial (DIN EN ISO 8192-OECD 209-88/302/EEC, P. C, aerobic)

Persistence and degradability

Assessment biodegradation and elimination (H₂O):

Not readily biodegradable (by OECD criteria). Biodegradable.

Elimination information:

90 - 100 % DOC reduction (21 d) (OECD Guideline 302 B) (aerobic, activated sludge, domestic)

Bioaccumulative potential

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Assessment bioaccumulation potential:

No data available.

Mobility in soil

Assessment transport between environmental compartments:

Adsorption in soil: No data available.

Results of PBT and vPvB assessment

According to Annex XIII of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self classification

Other adverse effects

The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

13. Disposal Considerations

Waste treatment methods

Observe national and local legal requirements.

14. Transport Information

Land transport

ADR

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

RID

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable

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Environmental hazards:	Not applicable
Special precautions for user	None known

Inland waterway transport

ADN

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	None known

Transport in inland waterway vessel

Not evaluated

Sea transport

IMDG

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

Air transport

IATA/ICAO

	Not classified as a dangerous good under transport regulations
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user	None known

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UN number

See corresponding entries for "UN number" for the respective regulations in the tables above.

UN proper shipping name

See corresponding entries for "UN proper shipping name" for the respective regulations in the tables above.

Transport hazard class(es)

See corresponding entries for "Transport hazard class(es)" for the respective regulations in the tables above.

Packing group

See corresponding entries for "Packing group" for the respective regulations in the tables above.

Environmental hazards

See corresponding entries for "Environmental hazards" for the respective regulations in the tables above.

Special precautions for user

See corresponding entries for "Special precautions for user" for the respective regulations in the tables above.

Transport in bulk according to Annex II of MARPOL and the IBC Code

Regulation:	Not evaluated
Shipment approved:	Not evaluated
Pollution name:	Not evaluated
Pollution category:	Not evaluated
Ship Type:	Not evaluated

15. Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

16. Other Information

Any other intended applications should be discussed with the manufacturer.

Full text of classifications, hazard symbols and hazard statements, if mentioned in section 2 or 3:
Aquatic Acute Hazardous to the aquatic environment - acute

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. This safety data sheet is neither a

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Certificate of Analysis (CoA) nor technical data sheet and shall not be mistaken for a specification agreement. Identified uses in this safety data sheet do neither represent an agreement on the corresponding contractual quality of the substance/mixture nor a contractually designated use. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

Vertical lines in the left hand margin indicate an amendment from the previous version.