

Safety data sheet

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

Date / Revised: 15.11.2019

Version: 3.0

Product: **Kolliphor® HS 15**

(ID no. 30554050/SDS_GEN_00/EN)

Date of print 18.11.2019

1. Identification

Product identifier

Kolliphor® HS 15

Chemical name: Octadecanoico ácido , 12 - hidroxí-, polímero con hidroxipoli alfa -hidro- .omega.- (oxi-1,2- etanodiilo),
CAS Number: 70142-34-6

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

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GERMANY

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2. Hazards Identification

Classification of the substance or mixture

According to UN GHS criteria

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Skin Sens. 1
| Aquatic Acute 3

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)

Pictogram:



Signal Word:
Warning

Hazard Statement:

H317 May cause an allergic skin reaction.
| H402 Harmful to aquatic life.

Precautionary Statements (Prevention):

| P280 Wear protective gloves.
| P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
| P273 Avoid release to the environment.
P272 Contaminated work clothing should not be allowed out of the workplace.

Precautionary Statements (Response):

P303 + P352 IF ON SKIN (or hair): Wash with plenty of soap and water.
| P333 + P311 If skin irritation or rash occurs: Call a POISON CENTER or
doctor/physician.
| P362 + P364 Take off contaminated clothing and wash it before reuse.

Precautionary Statements (Disposal):

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

Other hazards

According to UN GHS criteria

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

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Chemical nature

Octadecanoic acid, 12-hydroxy-, polymer with .alpha.-hydro-.omega.- hydroxypoly(oxy-1,2-ethanediyl)

CAS Number: 70142-34-6

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:

Keep patient calm, remove to fresh air, seek medical attention.

On skin contact:

After contact with skin, wash immediately with plenty of water and soap. If symptoms persist, seek medical advice.

On contact with eyes:

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. If irritation develops, seek medical attention.

On ingestion:

Immediately rinse mouth and then drink 200-300 ml of water, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: Information, i.e. additional information on symptoms and effects may be included in the GHS labeling phrases available in Section 2 and in the Toxicological assessments available in Section 11.

Indication of any immediate medical attention and special treatment needed

Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

5. Fire-Fighting Measures

Extinguishing media

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Suitable extinguishing media:
water spray, foam, dry powder, carbon dioxide

Special hazards arising from the substance or mixture

Burning produces harmful and toxic fumes.

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

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

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Pick up with suitable appliance and dispose of.
For large amounts: Pick up with suitable appliance and dispose of.
Dispose of absorbed material in accordance with regulations.

7. Handling and Storage

Precautions for safe handling

Ensure adequate ventilation. When handling heated product, vapours of the product should be ventilated, and respiratory protection used. Wear suitable protective clothing and eye/face protection.

Protection against fire and explosion:
Avoid all sources of ignition: heat, sparks, open flame.

Conditions for safe storage, including any incompatibilities

Further information on storage conditions: Containers should be stored tightly sealed in a dry 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

No occupational exposure limits known.

Exposure controls

Personal protective equipment

Respiratory protection:

Respiratory protection not required.

Hand protection:

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.

Eye protection:

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

Body protection:

Body protection must be chosen based on level of activity and exposure.

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Remove contaminated clothing. 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:	pasty
Colour:	white to slightly yellow
Odour:	almost odourless
Odour threshold:	
	not determined
pH value:	6 - 7 (100 g/l, 20 °C)
Melting point:	25 - 30 °C
Boiling point:	
	No data available.
Flash point:	272 °C

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Evaporation rate:		
Flammability:	negligible	
Lower explosion limit:	not highly flammable	(other)
Upper explosion limit:	For solids not relevant for classification and labelling.	
Ignition temperature:	360 °C	(DIN 51794)
Vapour pressure:	< 0,01 hPa (100 °C)	
Density:	1,03 g/cm ³ (60 °C)	(DIN 51757)
	1,048 g/cm ³ (20 °C)	
Relative vapour density (air):	negligible	
Solubility in water:	> 200 g/l (30 °C)	
Solubility (qualitative) solvent(s):	organic solvents soluble	
Partitioning coefficient n-octanol/water (log Kow):	not determined	
Thermal decomposition:	365 °C (DSC (DIN 51007)) self-accelerating reaction	
Viscosity, dynamic:	73 mPa.s (60 °C)	(DIN 53018)
Explosion hazard:	not explosive	(other)
Fire promoting properties:	not fire-propagating	(other)

Other information

Self heating ability: Not tested on account of the low melting-point.

10. Stability and Reactivity**Reactivity**

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

Corrosion to metals: No data available.

Formation of flammable gases: Remarks:

Forms no flammable gases in the presence of water.

Chemical stability

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The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions

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

Conditions to avoid

See SDS section 7 - Handling and storage.

Incompatible materials

Substances to avoid:

No substances known that should be avoided.

Hazardous decomposition products

Hazardous decomposition products:

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.

Experimental/calculated data:

LD50 rat (oral): > 20.600 mg/kg

Irritation

Assessment of irritating effects:

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

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405)

Respiratory/Skin sensitization

Assessment of sensitization:

Sensitization after skin contact possible.

Experimental/calculated data:

Guinea pig maximization test guinea pig: skin sensitizing (OECD Guideline 406)

Germ cell mutagenicity

Assessment of mutagenicity:

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

Reproductive toxicity

Assessment of reproduction toxicity:

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

Developmental toxicity

Assessment of teratogenicity:

In animal studies the substance did not cause malformations.

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

Assessment of repeated dose toxicity:

No adverse effects were observed after repeated exposure in animal studies.

Aspiration hazard

No data available.

12. Ecological Information

Toxicity

Assessment of aquatic toxicity:

Acutely harmful for aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish:

LC50 (96 h) > 100 mg/l, *Brachydanio rerio* (OECD 203; ISO 7346; 92/69/EEC, C.1, 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) > 100 mg/l (growth rate), *Desmodesmus subspicatus* (OECD Guideline 201, static)

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

Microorganisms/Effect on activated sludge:

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

Persistence and degradability

Assessment biodegradation and elimination (H₂O):
Readily biodegradable (according to OECD criteria).

Elimination information:

90 - 100 % DOC reduction (21 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)

Bioaccumulative potential

Assessment bioaccumulation potential:

Based on its structural properties, the polymer is not biologically available. Accumulation in organisms is not to be expected.

Mobility in soil

Assessment transport between environmental compartments:

Volatility: 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 product does not contain substances that are 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

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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
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

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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

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. Corresponding occupational protection measurements must be followed.

Full text of classifications, hazard symbols and hazard statements, if mentioned in section 2 or 3:

Skin Sens.	Skin sensitization
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 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.