

Safety data sheet

Page: 1/11

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

Date / Revised: 17.10.2017

Product: **Kolliphor® PS 80**

Version: 1.1

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

1. Identification

Product identifier

Kolliphor® PS 80

Chemical name: Sorbitanmonooleate with EO

CAS Number: 9005-65-6

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

No need for classification according to GHS criteria for this product.

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

Date / Revised: 17.10.2017

Product: **Kolliphor® PS 80**

Version: 1.1

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

Label elements

Globally Harmonized System, EU (GHS)

The product does not require a hazard warning label in accordance with GHS criteria.

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

Polyoxyethylene sorbitan monooleate
CAS Number: 9005-65-6

Ph. Eur.: Polysorbate 80

Mixtures

Not applicable

4. First-Aid Measures

Description of first aid measures

If adverse health effects develop seek medical attention.

If inhaled:

Fresh air.

On skin contact:

After contact with skin, wash immediately with plenty of water.

On contact with eyes:

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. Seek medical attention if necessary.

On ingestion:

BASF Safety data sheet according to UN GHS 4th rev.
Date / Revised: 17.10.2017
Product: **Kolliphor® PS 80**

Version: 1.1

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

Rinse mouth and then drink 200-300 ml of water.

Most important symptoms and effects, both acute and delayed

Symptoms: Overexposure may cause: , vomiting, diarrhea

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:

carbon dioxide, foam, dry powder, water spray, water jet

Unsuitable extinguishing media for safety reasons:

Unknown

Special hazards arising from the substance or mixture

carbon oxides

The substances/groups of substances mentioned can be released in case of fire. The product is combustible.

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. If exposed to fire, keep containers cool by spraying with water.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with the skin, eyes and clothing. Use personal protective clothing. Keep unprotected persons away. Information regarding personal protective measures see, section 8.

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 absorbent material. Dispose of absorbed material in accordance with regulations.

For large amounts: Dike spillage. Pump off product.

For residues: Pick up with suitable absorbent material. Dispose of absorbed material in accordance with regulations.

BASF Safety data sheet according to UN GHS 4th rev.
Date / Revised: 17.10.2017
Product: **Kolliphor® PS 80**

Version: 1.1

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

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**

Forms slippery surfaces with water. Keep container tightly closed. Avoid contact with skin and eyes.

Protection against fire and explosion:

Avoid open flames.

Conditions for safe storage, including any incompatibilities

Suitable materials for containers: High density polyethylene (HDPE), Stove-lacquer RDL 50

Further information on storage conditions: Keep only in the original container. Keep container tightly closed in a cool, well-ventilated 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

none

Exposure controls

Personal protective equipment

Respiratory protection:

Not applicable with adequate ventilation.

Hand protection:

Chemical resistant protective gloves (EN 374)

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:

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

Date / Revised: 17.10.2017

Version: 1.1

Product: **Kolliphor® PS 80**

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

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

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

9. Physical and Chemical Properties

Information on basic physical and chemical properties

Form:	oily	
Colour:	brown	
Odour:	odourless	
Odour threshold:	not applicable, odour not perceivable	
pH value:	6,5 - 7,5 (water, 20 °C)	(DGF-H-III 1)
Melting point:	-12 °C	
Boiling point:	> 100 °C (1.013 hPa)	
Flash point:	272 °C	(DIN ISO 2592)
Evaporation rate:	not determined	
Flammability:	hardly combustible	
Lower explosion limit:	For liquids not relevant for classification and labelling.	
Upper explosion limit:	For liquids not relevant for classification and labelling.	
Ignition temperature:	409 °C	(DIN EN 14522)
Vapour pressure:	1,2 hPa (25 °C)	
Density:	1,042 g/cm ³ (70 °C)	
Solubility (qualitative) solvent(s):	distilled water soluble, forms a gel	
Solubility (quantitative) solvent(s):	ethanol; ethyl alcohol, methanol	
Partitioning coefficient n-octanol/water (log Kow):	not determined	
Thermal decomposition:	No decomposition if stored and handled as prescribed/indicated.	
Viscosity, dynamic:	4.600 mPa*s (25 °C)	(DIN 53015)
Explosion hazard:	not explosive	
Fire promoting properties:	Based on its structural properties the product is not classified as oxidizing.	

Other information

Other Information:

If necessary, information on other physical and chemical parameters is indicated in this section.

10. Stability and Reactivity

Reactivity

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

Corrosion to metals: No corrosive effect on metal.

Chemical stability

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

Avoid all sources of ignition: heat, sparks, open flame. See MSDS section 7 - Handling and storage.

Incompatible materials

Substances to avoid:

No substances known that should be avoided.

Hazardous decomposition products

:

No hazardous decomposition products known.

11. Toxicological Information

Information on toxicological effects

Acute toxicity

Assessment of acute toxicity:

Virtually nontoxic after a single ingestion.

Experimental/calculated data:

LD50 (oral): > 5.000 mg/kg

Irritation

Assessment of irritating effects:

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

Date / Revised: 17.10.2017

Version: 1.1

Product: **Kolliphor® PS 80**

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

May cause slight irritation to the eyes. Not irritating to the skin.

Serious eye damage/irritation rabbit: non-irritant (Draize test)

Respiratory/Skin sensitization

Assessment of sensitization:

Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data:

Intracutaneous test guinea pig: Non-sensitizing.

Germ cell mutagenicity

Assessment of mutagenicity:

Results from a number of mutagenicity studies with microorganisms, mammalian cell culture and mammals are available. Taking into account all of the information, there is no indication that the substance is mutagenic.

Experimental/calculated data:

negative (Directive 84/449/EEC, B.14)

Carcinogenicity

Assessment of carcinogenicity:

The whole of the information assessable provides no indication of a carcinogenic effect.

Reproductive toxicity

Assessment of reproduction toxicity:

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

Developmental toxicity

Assessment of teratogenicity:

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

Specific target organ toxicity (single exposure)

Assessment of STOT single:

Based on available Data, the classification criteria are not met.

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:

There is a high probability that the product is not acutely harmful to 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 > 100 mg/l

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Microorganisms/Effect on activated sludge:

EC0 > 100 mg/l

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Persistence and degradability

Assessment biodegradation and elimination (H2O):

Not readily biodegradable (by OECD criteria). Moderately/partially biodegradable.

Elimination information:

Not readily biodegradable (by OECD criteria).

Bioaccumulative potential

Bioaccumulation potential:

Significant accumulation in organisms is not to be expected. The product has not been tested. The statement has been derived from the structure of the product.

Mobility in soil

Assessment transport between environmental compartments:

Adsorption in soil: No data available.

Results of PBT and vPvB assessment

According to Annex XIV 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.

Other adverse effects

BASF Safety data sheet according to UN GHS 4th rev.
Date / Revised: 17.10.2017
Product: **Kolliphor® PS 80**

Version: 1.1

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

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

13. Disposal Considerations

Waste treatment methods

Dispose of in accordance with national, state and local regulations.

Contaminated packaging:

Untamminated packaging can be re-used.

Packs that cannot be cleaned should be disposed of in the same manner as the contents.

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

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

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

Date / Revised: 17.10.2017

Version: 1.1

Product: **Kolliphor® PS 80**

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

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

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.

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

Date / Revised: 17.10.2017

Product: **Kolliphor® PS 80**

Version: 1.1

(ID no. 30554437/SDS_GEN_00/EN)

Date of print 18.10.2017

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

Assessment of the hazard classes according to UN GHS criteria (most recent version)

Any other intended applications should be discussed with the manufacturer. Corresponding occupational protection measurements must be followed.

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.