

Revision date : 2020/06/18 Version: 4.0 Page: 1/9 (30554436/SDS_GEN_US/EN)

1. Identification

Product identifier used on the label

Kolliphor® PS 20

Recommended use of the chemical and restriction on use

Recommended use*: pharmaceutical excipient

* The "Recommended use" identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

<u>Company:</u> BASF CORPORATION 100 Park Avenue Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

Emergency telephone number

CHEMTREC: 1-800-424-9300 BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

Synonyms: Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Classification of the product

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

Label elements

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

Revision date : 2020/06/18 Version: 4.0

Hazards not otherwise classified

High risk of slipping due to leakage/spillage of product.

3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Under the referenced regulation, this product does not contain any components classified for health hazards above the relevant cut off value.

4. First-Aid Measures

Description of first aid measures

General advice:

If symptoms persist, seek medical advice.

If inhaled:

Fresh air.

If on skin:

Wash thoroughly with soap and water If irritation develops, seek medical attention.

If in eyes:

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

If swallowed:

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

Most important symptoms and effects, both acute and delayed

Symptoms: (Further) symptoms and / or effects are not known so far

Indication of any immediate medical attention and special treatment needed

Note to physician Treatment:

Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

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

Unsuitable extinguishing media for safety reasons: water jet

Special hazards arising from the substance or mixture

Revision date : 2020/06/18 Version: 4.0

Page: 3/9 (30554436/SDS GEN US/EN)

Hazards during fire-fighting:

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

Advice for fire-fighters

Protective equipment for fire-fighting: Wear a self-contained breathing apparatus.

Further information:

If exposed to fire, keep containers cool by spraying with water. 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. Use personal protective clothing. 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.

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.

Protection against fire and explosion:

Avoid all sources of ignition: heat, sparks, open flame. Take precautionary measures against static discharges. The product is combustible.

Conditions for safe storage, including any incompatibilities

Suitable materials for containers: High density polyethylene (HDPE)

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

8. Exposure Controls/Personal Protection

No occupational exposure limits known.

Revision date : 2020/06/18 Version: 4.0

Personal protective equipment

Respiratory protection:

Not applicable with adequate ventilation.

Hand protection:

Wear chemical resistant protective gloves.

Eye protection:

Wear face shield or tightly fitting safety goggles (chemical goggles) if splashing hazard exists.

Body protection:

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

General safety and hygiene measures:

Avoid contact with the skin, eyes and clothing. 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

Form: Odour: Odour threshold: Colour: pH value:	liquid faint, sweetish not applicable, odour not perceivable light yellow 6.0 - 7.5 (20 °C)	(ISO 4316)
Melting temperature:	approx. 15 °C	
Freezing point:	approx. 15 °C	
Boiling point:	> 100 °C	
Flash point:	> 110.0 °C	(DIN ISO 2592)
Flammability:	hardly combustible	
Lower explosion limit:	For liquids not relevant for	
	classification and labelling.	
Upper explosion limit:	For liquids not relevant for	
A	classification and labelling.	
Autoignition:	not determined	
Vapour pressure:	< 1.33 hPa	
Descit	(20 °C)	
Density:	1.0 - 1.2 g/cm3	
De difference en effecte et e	(20 °C)	
Partitioning coefficient n-	not determined	
octanol/water (log Pow):		
Viscosity, dynamic:	not determined	
Viscosity, kinematic:	No data available.	
Solubility in water:	(20 °C) soluble	
Molar mass:	No data available.	
Evaporation rate:	Value can be approximated from	
	Henry's Law Constant or vapor	
	pressure.	
Other Information:	If necessary, information on other physic parameters is indicated in this section.	
	available.	

10. Stability and Reactivity

Reactivity

Revision date : 2020/06/18 Version: 4.0

Page: 5/9 (30554436/SDS_GEN_US/EN)

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

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

Oxidizing properties: not fire-propagating Formation of Remarks: flammable gases:

Forms no flammable gases in the presence of water.

Chemical stability

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

Possibility of hazardous reactions

The product is stable if stored and handled as prescribed/indicated. No hazardous reactions if stored and handled as prescribed/indicated.

Conditions to avoid

See SDS section 7 - Handling and storage.

Incompatible materials

strong oxidizing agents

Hazardous decomposition products

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

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Virtually nontoxic after a single ingestion. Of low toxicity after short-term skin contact.

<u>Oral</u> Type of value: LD50 Species: rat Value: > 5,000 mg/kg (BASF-Test)

Inhalation No data available.

Dermal Type of value: LD50 Species: rabbit Value: > 3,000 mg/kg Literature data.

Revision date : 2020/06/18 Version: 4.0

Assessment other acute effects

Assessment of STOT single: Based on the available information there is no specific target organ toxicity to be expected after a single exposure.

Irritation / corrosion Assessment of irritating effects: May cause slight irritation to the eyes. Not irritating to the skin.

<u>Skin</u> No data available.

<u>Eye</u> Species: rabbit Result: Slightly irritating. Method: OECD Guideline 405

<u>Sensitization</u> Assessment of sensitization: There is no evidence of a skin-sensitizing potential.

<u>Aspiration Hazard</u> No aspiration hazard expected.

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: The information available on the product provides no indication of toxicity on target organs after repeated exposure.

Genetic toxicity

Assessment of mutagenicity: No data was available concerning mutagenic activity.

Carcinogenicity

Assessment of carcinogenicity: No data was available concerning carcinogenic activity.

Reproductive toxicity

Assessment of reproduction toxicity: No data available.

Teratogenicity

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

12. Ecological Information

Toxicity

Aquatic toxicity Assessment of aquatic toxicity: There is a high probability that the product is not acutely harmful to aquatic organisms.

Toxicity to fish LC50 > 100 mg/l (DIN EN ISO 7346-2)

<u>Aquatic invertebrates</u> EC50 (48 h) > 10 mg/l, Daphnia magna (OECD Guideline 202, part 1, static)

Revision date : 2020/06/18 Version: 4.0

Page: 7/9 (30554436/SDS GEN US/EN)

Literature data. The details of the toxic effect relate to the nominal concentration. Limit concentration test only (LIMIT test).

<u>Aquatic plants</u> EC50 > 100 mg/l (growth rate), Selenastrum capricornutum The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to aquatic invertebrates

EC10 (21 d) 10 mg/l, Daphnia magna (OECD Guideline 202, part 2, static) Literature data. The details of the toxic effect relate to the nominal concentration. Limit concentration test only (LIMIT test).

<u>Assessment of terrestrial toxicity</u> No data available concerning terrestrial toxicity.

Microorganisms/Effect on activated sludge

Toxicity to microorganisms DIN 38412 Part 27 (draft) EC0: > 100 mg/l

Persistence and degradability

Assessment biodegradation and elimination (H2O) Biodegradable.

Elimination information

> 70 % DOC reduction (28 d) (OECD 303A; ISO 11733; 92/69 EEC,V, C.10) (aerobic, activated sludge)

Bioaccumulative potential

<u>Assessment bioaccumulation potential</u> Accumulation in organisms is not to be expected.

Bioaccumulation potential No data available.

Mobility in soil

Assessment transport between environmental compartments No data available.

Additional information

Other ecotoxicological advice: No data available.

13. Disposal considerations

Waste disposal of substance:

Observe national and local legal requirements.

Container disposal:

Uncontaminated packaging can be re-used. Packs that cannot be cleaned should be disposed of in the same manner as the contents.

Revision date : 2020/06/18 Version: 4.0

14. Transport Information

Land transport USDOT	
	Not classified as a dangerous good under transport regulations
Sea transport IMDG	
	Not classified as a dangerous good under transport regulations

Air transport IATA/ICAO

Not classified as a dangerous good under transport regulations

15. Regulatory Information

Federal Regulations

Registration status:

Chemical	TSCA, US	released /	/ listed
Chemical	15CA, US	released /	listec

Pharma TSCA, US released / exempt

EPCRA 311/312 (Hazard categories): Refer to SDS section 2 for GHS hazard classes applicable for this product.

NFPA Hazard codes: Health: 1 Fire: 1 Reacti

1 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 1 Flammability: 1 Physical hazard:0

16. Other Information

SDS Prepared by:

BASF NA Product Regulations SDS Prepared on: 2020/06/18

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Revision date : 2020/06/18 Version: 4.0 Page: 9/9 (30554436/SDS GEN US/EN)

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END OF DATA SHEET