

Safety data sheet

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

Date / Revised: 30.04.2019

Version: 6.0

Product: **Kolliphor® P 338**

(ID no. 30555125/SDS_GEN_00/EN)

Date of print 01.05.2019

1. Identification

Product identifier

Kolliphor® P 338

Chemical name: Methyl-oxirane polymer with oxirane

CAS Number: 9003-11-6

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

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.

Label elements

Globally Harmonized System (GHS)

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

Other hazards

According to UN GHS criteria

No specific dangers known, if the regulations/notes for storage and handling are considered.

3. Composition/Information on Ingredients

Substances

Chemical nature

Oxirane, methyl-, polymer with oxirane
CAS Number: 9003-11-6

Mixtures

Not applicable

4. First-Aid Measures

Description of first aid measures

If inhaled:

Keep patient calm, remove to fresh air.

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

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:

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water spray, dry powder, foam

Special hazards arising from the substance or mixture

harmful vapours

Evolution of fumes/fog. The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters

Special protective equipment:

Wear a self-contained breathing apparatus.

Further information:

Contaminated extinguishing water must be disposed of in accordance with official regulations.

6. Accidental Release Measures

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

Personal precautions, protective equipment and emergency procedures

Use personal protective clothing. Information regarding personal protective measures see, section 8.

Environmental precautions

Contain contaminated water/firefighting water. Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Sweep/shovel up.

For large amounts: Sweep/shovel up.

Avoid raising dust. Dispose of absorbed material in accordance with regulations.

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

No special measures necessary provided product is used correctly.

Protection against fire and explosion:

No special precautions necessary.

Conditions for safe storage, including any incompatibilities

Suitable materials for containers: Stainless steel 1.4401, High density polyethylene (HDPE), Low density polyethylene (LDPE)

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

Storage stability:

Store in unopened original containers in a cool and 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 controlsPersonal protective equipment

Respiratory protection:

Respiratory protection in case of vapour/aerosol release.

Hand protection:

Chemical resistant protective gloves (EN 374)

Suitable materials also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374):

nitrile rubber (NBR) - 0.4 mm coating thickness

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)

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended.

9. Physical and Chemical Properties**Information on basic physical and chemical properties**

Form:	prills, cast solid, pastilles, molten
Colour:	white to cream
Odour:	mild, of polyol
pH value:	6 - 7,4
Melting temperature:	approx. 52 °C (1.013 hPa)

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Boiling point:	The product has not been tested., The product is a non-volatile solid.	
Flash point:	approx. 257 °C	(ASTM D92)
Flammability:	No data available.	
Lower explosion limit:	not applicable	
Upper explosion limit:	not applicable	
Ignition temperature:	No data available.	
Vapour pressure:	< 0,1 mmHg (25 °C)	
Density:	1,06 g/cm ³ (77 °C)	
Solubility in water:	soluble	
Partitioning coefficient n-octanol/water (log Kow):	-1,58	(calculated)
Self ignition:	not self-igniting	
Thermal decomposition:	No data available.	
Viscosity, dynamic:	1.600 mPa.s (93,3 °C)	
Explosion hazard:	not explosive	
Fire promoting properties:	not fire-propagating	

Other information

Bulk density:	1.050 kg/m ³
Surface tension:	No data available.
Grain size distribution:	The substance / product is marketed or used in a non solid or granular form.
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 when stored and handled according to instructions.

Conditions to avoid

See MSDS 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): > 2.000 mg/kg

LC50 rat (by inhalation):

not determined

ATE (dermal): > 5.000 mg/kg

Irritation

Assessment of irritating effects:

Not irritating to eyes and skin.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (Draize test)

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

Respiratory/Skin sensitization

Assessment of sensitization:

No data available.

Germ cell mutagenicity

Assessment of mutagenicity:

No data was available concerning mutagenic activity.

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Carcinogenicity

Assessment of carcinogenicity:

No data was available concerning carcinogenic activity.

Reproductive toxicity

Assessment of reproduction toxicity:

No data available.

Developmental toxicity

Assessment of teratogenicity:

No data available.

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

Assessment of repeated dose toxicity:

No data available.

Aspiration hazard

No data available.

Other relevant toxicity information

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

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

Toxicity to fish:

LC50 (96 h) > 100 mg/l, *Leuciscus idus*

Analogous: Assessment derived from products with similar chemical character.

Aquatic invertebrates:

EC50 (48 h) > 100 mg/l, *Daphnia magna*

Analogous: Assessment derived from products with similar chemical character.

Aquatic plants:

EC50 (72 h) > 100 mg/l

Analogous: Assessment derived from products with similar chemical character.

Microorganisms/Effect on activated sludge:

Inhibition of degradation activity in activated sludge is not to be anticipated during correct introduction of low concentrations.

Analogous: Assessment derived from products with similar chemical character.

Chronic toxicity to fish:

No data available.

Chronic toxicity to aquatic invertebrates:

No data available.

Assessment of terrestrial toxicity:

No data available concerning terrestrial toxicity.

Persistence and degradability

Assessment biodegradation and elimination (H₂O):

is partially eliminated in sewage treatment plants

Elimination information:

approx. 70 - 80 % CO₂ formation relative to the theoretical value (28 d) (OECD 301B; ISO 9439; 92/69/EEC, C.4-C) (aerobic, activated sludge, domestic) Readily biodegradable.

Bioaccumulative potential

Assessment bioaccumulation potential:

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

Bioaccumulation potential:

Accumulation in organisms is not to be expected.

Mobility in soil

Assessment transport between environmental compartments:

Volatility: not determined

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. Self classification

Other adverse effects

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The product does not contain substances that are listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

Additional information

Add. remarks environm. fate & pathway:

Treatment in biological waste water treatment plants has to be performed according to local and administrative regulations.

13. Disposal Considerations

Waste treatment methods

Must be disposed of or incinerated in accordance with local regulations.

Contaminated packaging:

Uncontaminated 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

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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

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

Information on intended use: This product is of industrial quality and unless otherwise specified or agreed intended exclusively for industrial use. This includes the mentioned and recommended usage. Any other intended applications should be discussed with the manufacturer. In particular this concerns the application for products that are the object of special standards and regulations.

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.