

Safety data sheet

Page: 1/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

1. Identification

Product identifier

Kolliphor® P 188 micro

Chemical name: Oxirane, methyl-, 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

<u>Company:</u> 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.

Page: 2/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

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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

Avoid dust development and deposition - dust explosion risk. Take precautionary measures against static discharges. 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

block copolymer Oxirane, 2-methyl-, polymer with oxirane CAS Number: 9003-11-6

Ph. Eur.: Poloxamer 188

Mixtures

Not applicable

4. First-Aid Measures

Description of first aid measures

Remove contaminated clothing.

If inhaled: Keep patient calm, remove to fresh air.

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:

Page: 3/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

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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, dry powder, carbon dioxide

Unsuitable extinguishing media for safety reasons: water jet

Additional information: Avoid whirling up the material/product because of the danger of dust explosion.

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. The degree of risk is governed by the burning substance and the fire conditions. Dust can form an explosive mixture with air.

6. Accidental Release Measures

Avoid the formation and build-up of dust - danger of dust explosion. Dust in sufficient concentration can result in an explosive mixture in air. Handle to minimize dusting and eliminate open flame and other sources of ignition.

Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid all sources of ignition: heat, sparks, open flame. 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.

Page: 4/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

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Methods and material for containment and cleaning up

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

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

Ensure thorough ventilation of stores and work areas. Provide exhaust ventilation if dust is formed. Take precautionary measures against static discharges. Use antistatic tools.

Protection against fire and explosion:

Fine dust of the product is capable of dust explosion. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Conditions for safe storage, including any incompatibilities

Further information on storage conditions: Protect against heat. Keep container tightly closed in a cool, well-ventilated place. Avoid dust formation. Take precautionary measures against static discharges.

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: Breathing protection if dusts are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1or FFP1)

Hand protection:

Manufacturer's directions for use should be observed because of great diversity of types.

Page: 5/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

Chemical resistant protective gloves (EN 374)

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

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

9. Physical and Chemical Properties

Information on basic physical and chemical properties

	n ou udou
Form:	powder white
Colour:	
Odour:	faint specific odour
Odour threshold:	
	not applicable
pH value:	5 - 7,5
	(10 g/l, 20 °C)
Melting point:	52 °C
Boiling point:	
51	The product is a non-volatile solid.
Flash point:	260 °C
Flammability:	not highly flammable
Lower explosion limit:	not niginy hannable
Lower explosion mint.	For solids not relevant for
	classification and labelling.
Upper explosion limit:	For collide not college then
	For solids not relevant for
	classification and labelling.
Ignition temperature:	290 °C
Vapour pressure:	
	negligible
Density:	
-	No data available.
Relative vapour density	(air):
. ,	The product is a non-volatile solid.
Solubility in water:	•
,, ,	> 100 g/l
Partitioning coefficient n-	-octanol/water (log Kow):
g eee word and a second of the the	not applicable
Thermal decomposition:	No decomposition if stored and handled as prescribed/indicated.
	no accomposition in stored and nandica as presenbed/indicated.

Page: 6/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

Viscosity, dynamic:		
Explosion hazard:	not applicable, the product is a solid Product is not explosive, however a dust explosion could result from an air / dust mixture.	
Other information		
Self heating ability:	It is not a substance capable of spontaneous heating.	
Minimum ignition energy	: > 1 - < 10 J The product is capable of dust explosion.	
Bulk density:	400 kg/m3	

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.	
Formation of	Remarks:	Forms no flammable gases in the
flammable gases:		presence of water.

Chemical stability

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

Possibility of hazardous reactions

The product may contain explosive fine dust or such dust may be produced by abrasion during transport or product transfer.

Conditions to avoid

Avoid dust formation. See MSDS section 7 - Handling and storage.

Incompatible materials

Substances to avoid: strong bases, strong acids, strong oxidizing agents

Hazardous decomposition products

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

Page: 7/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

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.

Experimental/calculated data: LD50 rat (oral): > 5.000 mg/kg (BASF-Test) The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

LD50 rabbit (dermal): > 2.000 mg/kg The product has not been tested. The statement has been derived from substances/products of a similar structure or composition. Literature data.

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

Serious eye damage/irritation rabbit: non-irritant (OECD Guideline 405) The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Respiratory/Skin sensitization

Assessment of sensitization: Skin sensitizing effects were not observed in animal studies.

Germ cell mutagenicity

Assessment of mutagenicity: The substance was not mutagenic in bacteria.

Carcinogenicity

Assessment of carcinogenicity:

In long-term studies in rats in which the substance was given by feed, a carcinogenic effect was not observed. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition. Literature data.

Reproductive toxicity

Page: 8/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

Assessment of reproduction toxicity:

The results of animal studies gave no indication of a fertility impairing effect. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition. Literature data.

Developmental toxicity

Assessment of teratogenicity:

No indications of a developmental toxic / teratogenic effect were seen in animal studies. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition. Literature data.

12. Ecological Information

Toxicity

Assessment of aquatic toxicity:

The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations. There is a high probability that the product is not acutely harmful to aquatic organisms.

Toxicity to fish: LC50 (96 h) > 120 mg/l, Oncorhynchus mykiss (OECD 203; ISO 7346; 92/69/EEC, C.1, static)

Aquatic invertebrates: EC50 (48 h) > 100 mg/l, Daphnia magna (Directive 79/831/EEC, static) Nominal concentration. Analogous: Assessment derived from products with similar chemical character.

Aquatic plants: EC50 (72 h) > 100 mg/l (biomass), Scenedesmus subspicatus (DIN 38412 Part 9, static) Nominal concentration. Analogous: Assessment derived from products with similar chemical character.

Microorganisms/Effect on activated sludge: EC50 (30 min) > 1.000 mg/l, activated sludge, domestic (OECD Guideline 209, aquatic) Nominal concentration.

Persistence and degradability

Assessment biodegradation and elimination (H2O): Not readily biodegradable (by OECD criteria). Poorly biodegradable.

Elimination information:

0 - 10 % DOC reduction (28 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic) Not readily biodegradable (by OECD criteria).

Bioaccumulative potential

Page: 9/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

Bioaccumulation potential: Significant accumulation in organisms is not to be expected.

Mobility in soil

Assessment transport between environmental compartments: Adsorption in soil: Adsorption to solid soil phase is expected.

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. Incinerate in suitable incineration plant, observing local authority regulations.

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

14. Transport Information

Land transport

UN number:

Packing group:

Environmental hazards:

Special precautions for

ADR

Not classified as a dangerous good under transport regulations Not applicable Not applicable UN proper shipping name: Transport hazard class(es): Not applicable Not applicable Not applicable None known

RID

user

Page: 10/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

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

Inland waterway transport ADN

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

Transport in inland waterway vessel Not evaluated

Sea transport

IMDG

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

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

Page: 11/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

Date of print 03.08.2017

Environmental hazards: Not applicable Special precautions for None known user

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

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

Page: 12/12

BASF Safety data sheet according to UN GHS 4th rev. Date / Revised: 14.10.2016 Product: Kolliphor® P 188 micro

Version: 1.1

(ID no. 30554049/SDS_GEN_00/EN)

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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.