

Safety Data Sheet Kolliphor® P 188 special

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Version: 3.3 (30570274/SDS_GEN_US/EN)

1. Identification

Product identifier used on the label

Kolliphor® P 188 special

Recommended use of the chemical and restriction on use

Recommended use*: pharmaceutical excipient

Details of the supplier of the safety data sheet

Company: 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: Oxirane, methyl-, polymer with oxirane

2. Hazards Identification

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

Classification of the product

Combustible Dust Combustible Dust (1) Combustible Dust

Label elements

Signal Word: Warning

Hazard Statement:

^{*} 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.

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May form combustible dust concentration in air.

Hazards not otherwise classified

The product is under certain conditions capable of dust explosion.

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:

Remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air.

If on skin:

Wash thoroughly with soap and water

If in eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open.

If swallowed:

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

Most important symptoms and effects, both acute and delayed

Symptoms: No data available.

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: water spray, foam, dry powder

Unsuitable extinguishing media for safety reasons: water jet

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Special hazards arising from the substance or mixture

Hazards during fire-fighting: carbon oxides, harmful vapours

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

Dust explosion hazard.

Advice for fire-fighters

Protective equipment for fire-fighting:

Wear a self-contained breathing apparatus.

Further information:

Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Dusty conditions may ignite explosively in the presence of an ignition source causing flash fire.

6. Accidental release measures

Further accidental release measures:

Avoid the formation and build-up of dust - danger of dust explosion. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). 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

Use personal protective clothing. Information regarding personal protective measures, see section 8. Avoid dust formation. Avoid contact with the skin, eyes and clothing.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For large amounts: Sweep/shovel up.

For residues: Contain with dust binding material and dispose of.

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

For small amounts: Sweep/shovel up. Place into suitable container for disposal. For large amounts: Sweep/shovel up. Place into covered container for disposal.

Avoid raising dust. Nonsparking tools should be used.

7. Handling and Storage

Precautions for safe handling

Avoid dust formation. Provide exhaust ventilation if dust is formed.

Protection against fire and explosion:

Avoid dust formation. 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. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Refer to NFPA 654,

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Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids (2013 Edition) for safe handling.

Dust explosion class: Dust explosion class 1 (Kst-value >0 up to 200 bar m s-1).

Conditions for safe storage, including any incompatibilities

No applicable information available.

Further information on storage conditions: Keep container tightly closed and dry. Protect against heat.

8. Exposure Controls/Personal Protection

No occupational exposure limits known.

Advice on system design:

It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection:

Breathing protection if breathable aerosols/dust are formed.

Hand protection:

Wear chemical resistant protective gloves.

Eye protection:

Wear safety goggles (chemical goggles) if there is potential for airborne dust exposures.

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. Wearing of closed work clothing is recommended. Eye wash fountains and safety showers must be easily accessible. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately.

9. Physical and Chemical Properties

Form: powder
Odour: faint, of polyol
Colour: white

pH value: 5 - 7.5

(10 g/l, 20 °C)

Melting point: 52 °C Freezing point: 52 °C

Boiling point: The product is a non-volatile solid. Sublimation point: No applicable information available.

Flash point: 260 °C

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Flammability: not highly flammable (VDI 2263, sheet 1,

all land and and the

Lower explosion limit: For solids not relevant for

classification and labelling. For solids not relevant for

Upper explosion limit: For solids not relevant for classification and labelling.

Autoignition: 290 °C Vapour pressure: negligible

Bulk density: approx. 500 kg/m3

Vapour density: The product is a non-volatile solid.

Partitioning coefficient n- not applicable

octanol/water (log Pow):

Self-ignition The value has not be determined temperature: because of the low risk of self-ignition in consequence of the low melting

point.

Thermal decomposition: No decomposition if stored and handled as

prescribed/indicated.

Viscosity, dynamic: not applicable, the product is a solid

Viscosity, kinematic: not applicable Solubility in water: > 100 g/l

soluble

Solubility (qualitative): soluble

solvent(s): organic solvents,

Molar mass: not applicable

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.

Dust explosivity characteristics:

Kst: 18 m.bar/s

Dust explosion class:

Dust explosion class 1 (Kst-value >0 up to 200 bar m s-1) (St 1)

Minimum ignition energy:

> 1 - < 10 J

The product is capable of dust explosion.

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. Avoid all sources of ignition: heat, sparks, open flame. Avoid electro-static charge.

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Incompatible materials

strong oxidizing agents, strong bases, strong acids

Hazardous decomposition products

Decomposition products:

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

Thermal decomposition:

No decomposition 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. Virtually nontoxic after a single skin contact.

Oral

Type of value: LD50

Species: rat

Value: > 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.

Inhalation

No data available.

Dermal

Type of value: LD50 Species: rabbit Value: > 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.

Assessment other acute effects

No applicable information available.

Irritation / corrosion

Assessment of irritating effects: Not irritating to the skin. Not irritating to the eyes.

Skin

Species: rabbit Result: non-irritant

Method: OECD Guideline 404

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

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Eye

Species: rabbit Result: non-irritant

Method: OECD Guideline 405

The product has not been tested. The statement has been derived from substances/products of a

similar structure or composition.

Sensitization

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

Aspiration Hazard

No data available.

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: No data available.

Experimental/calculated data: No data available.

Genetic toxicity

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

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.

Teratogenicity

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

Aquatic 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

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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.

Assessment of terrestrial toxicity

No data available.

Microorganisms/Effect on activated sludge

<u>Toxicity to microorganisms</u>
OECD Guideline 209 aquatic
activated sludge, domestic/EC50 (30 min): > 1,000 mg/l
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

Bioaccumulation potential

Significant accumulation in organisms is not to be expected.

Mobility in soil

Assessment transport between environmental compartments

Adsorption to solid soil phase is expected.

Additional information

Other ecotoxicological advice:

No data available.

13. Disposal considerations

Waste disposal of substance:

Observe national and local legal requirements.

Container disposal:

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

14. Transport Information

Land transport

USDOT

Not classified as a dangerous good under transport regulations

Sea transport

IMDG

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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:

Pharma TSCA, US released / exempt

Chemical TSCA, US released / listed

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

NFPA Hazard codes:

Health: 0 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 0 Flammability: 1 Physical hazard: 0

16. Other Information

SDS Prepared by:

BASF NA Product Regulations SDS Prepared on: 2020/06/19

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END OF DATA SHEET