

Safety data sheet

Page: 1/9

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 21.09.2011

Version: 5.0

Product: **Kollidon® 90 F**

(ID no. 30034978/SDS_GEN_EU/EN)

Date of print 22.09.2011

1. Identification of the substance/mixture and of the company/undertaking

Product identifier

Kollidon® 90 F

Chemical name: 2-Pyrrolidinone, 1-ethenyl-, homopolymer

CAS Number: 9003-39-8

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-Masterdata@basf.com

Emergency telephone number

International emergency number:

Telephone: +49 180 2273-112

2. Hazards Identification

Label elements

According to Regulation (EC) No 1272/2008 [CLP]

Globally Harmonized System, EU (GHS)

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

According to Directive 67/548/EEC or 1999/45/EC

The product does not require a hazard warning label in accordance with EC Directives.

Classification of the substance or mixture

According to Regulation (EC) No 1272/2008 [CLP]

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

According to Directive 67/548/EEC or 1999/45/EC

Possible Hazards:
No particular hazards known.

Other hazards

According to Regulation (EC) No 1272/2008 [CLP]

Other Hazards (GHS):
If applicable information is provided in this section on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture.

3. Composition/Information on Ingredients

Substances

Chemical nature

polyvinylpyrrolidone

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:
Immediately rinse mouth and then drink plenty of water, do not induce vomiting, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: No data available.

Hazards: No data available.

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

Special hazards arising from the substance or mixture

carbon dioxide, cyanides, nitrogen oxides

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:

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 dust formation.

Environmental precautions

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.

Dispose of absorbed material in accordance with regulations.

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**

Handle in accordance with good industrial hygiene and safety practice.

Protection against fire and explosion:

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: Containers should be stored tightly sealed in a dry place. Protect against heat.

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

Exposure controls

Personal protective equipment

Respiratory protection:

Breathing protection if breathable aerosols/dust are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1 or FFP1)

Hand protection:

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other
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.

Eye protection:

Safety glasses with side-shields (frame goggles) (e.g. EN 166)

Body protection:

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

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Information on basic physical and chemical properties

| | | |
|------------------|-------------------------|------------------|
| Form: | powder | |
| Colour: | white to cream | |
| Odour: | faint specific odour | |
| Odour threshold: | | |
| | No data available. | |
| pH value: | 5.0 - 9.0 | (Ph. Eur. 2.2.3) |
| | (water, 10 %(m), 20 °C) | |

BASF Safety data sheet according to Regulation (EC) No. 1907/2006

Date / Revised: 21.09.2011

Version: 5.0

Product: **Kollidon® 90 F**

(ID no. 30034978/SDS_GEN_EU/EN)

Date of print 22.09.2011

| | | |
|---|--|-------------|
| melting range: | >= 130 °C The substance / product decomposes. | |
| Boiling point: | The product is a non-volatile solid. | |
| Flash point: | > 215 °C | (DIN 51755) |
| Evaporation rate: | No data available. | |
| Flammability: | No data available. | |
| Lower explosion limit: | 50 g/m ³ | (air) |
| Upper explosion limit: | No data available. | |
| Ignition temperature: | 425 °C | (DIN 51794) |
| Vapour pressure: | No data available. | |
| Density: | 1.2 g/cm ³ (20 °C) | |
| Relative density: | No data available. | |
| Relative vapour density (air): | No data available. | |
| Solubility in water: | > 270 g/l (23 °C) | |
| Solubility (qualitative) solvent(s): | organic solvents soluble | |
| <i>Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer</i> | | |
| <i>Partitioning coefficient n-octanol/water (log Kow): -3.4</i> | | |
| ----- | | |
| Self ignition: | not self-igniting | |
| Thermal decomposition: | >= 130 °C | |
| Explosion hazard: | not explosive | |
| Fire promoting properties: | not fire-propagating | |

Other information

| | | |
|--------------------------|---|--------------------------|
| Minimum ignition energy: | 10 - 30 mJ (approx. 1 bar, approx. 23 °C) The product is capable of dust explosion. | (VDI 2263, sheet 1, 2.5) |
| Bulk density: | approx. 400 - 600 kg/m ³ | (DIN EN ISO 60) |
| Miscibility with water: | soluble | |

10. Stability and Reactivity**Reactivity**

| | | |
|-------------------------------|---|--|
| Corrosion to metals: | Corrosive effects to metal are not anticipated. | |
| Formation of flammable gases: | Remarks: | 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

Dust explosion hazard.

Conditions to avoid

Avoid dust formation.

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. Virtually nontoxic by inhalation.

Experimental/calculated data:

LD50 rat (oral): > 2,000 mg/kg (BASF-Test)

LC50 rat (by inhalation): > 5.2 mg/l 4 h (OECD Guideline 403)

Irritation

Assessment of irritating effects:

Not irritating to the skin. Not irritating to the eyes.

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:

The chemical structure does not suggest a sensitizing effect.

Germ cell mutagenicity

Assessment of mutagenicity:

The substance was not mutagenic in studies with mammals.

Carcinogenicity

Assessment of carcinogenicity:

In long-term animal studies in which the substance was given in high doses by feed, a carcinogenic effect was not observed.

Reproductive toxicity**Assessment of reproduction toxicity:**

No data available concerning reproduction toxicity.

Developmental toxicity**Assessment of teratogenicity:**

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

Other relevant toxicity information

Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses. The product has not been tested. The statement has been derived from 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.

Toxicity to fish:

LC50 (96 h) > 10,000 mg/l, *Leuciscus idus* (DIN 38412 Part 15, static)

Microorganisms/Effect on activated sludge:

EC20 (0.5 h) > 1,995 mg/l, activated sludge, industrial (OECD Guideline 209, aerobic)

Persistence and degradability

Assessment biodegradation and elimination (H₂O):

Poorly eliminated from water.

Elimination information:

< 10 % DOC reduction (15 d) (OECD Guideline 302 B) (aerobic, activated sludge, industrial) Poorly eliminated from water.

Bioaccumulative potential

Bioaccumulation potential:

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

Mobility in soil (and other compartments if available)

Assessment transport between environmental compartments:

No data available.

Results of PBT and vPvB assessment

According to Regulation (EC) No.453/2010: The product does not fulfill the criteria for PBT (persistent/bioaccumulative/toxic) or vPvB (very persistent/very bioaccumulative).

Other adverse effects

No data available.

Additional information

Other ecotoxicological advice:
Ecological data are determined by analogy.

13. Disposal Considerations

Waste treatment methods

Must be sent to a suitable incineration plant, observing local regulations.
A waste code in accordance with the European waste catalog (EWC) cannot be specified, due to dependence on the usage.
Observe national and local legal requirements.

14. Transport Information

Land transport

ADR

Not classified as a dangerous good under transport regulations

RID

Not classified as a dangerous good under transport regulations

Inland waterway transport

ADN

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

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.

Chemical Safety Assessment

Chemical Safety Assessment not required

16. Other Information

Any other intended applications should be discussed with the manufacturer.

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. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. 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.