

# Safety data sheet

Page: 1/9

BASF Safety data sheet  
Date / Revised: 15.03.2024  
Product: **Kollidon® 12 PF**

Version: 4.1

(30034972/SDS\_GEN\_AU/EN)

Date of print: 13.10.2025

## 1. Substance/preparation and manufacturer/supplier identification

**Product name:**  
**Kollidon® 12 PF**

Use: pharmaceutical excipient

Manufacturer/supplier:

BASF Australia Limited (ABN 62 008 437 867)  
Level 23, 40 City Road, Southbank  
Victoria 3006, AUSTRALIA  
Telephone: +61 3 8855-6600

Emergency information:

BASF Emergency Advice Number: 1800 803 440 (24h) [within Australia]  
BASF Emergency Advice Number: + 61 3 8855 6666 [outside Australia]

## 2. Hazard identification

Classification of the substance and mixture:

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

Label elements and precautionary statement:

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

Other hazards which do not result in classification:

The product is under certain conditions capable of dust explosion.

## 3. Composition/information on ingredients

Chemical nature

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Substance nature: Substance

2-Pyrrolidinone, 1-ethenyl-, homopolymer

**Hazardous ingredients**

lactic acid

Content (W/W): &gt; 0 % - &lt; 0.2 %

CAS Number: 50-21-5

Acute Tox.: Cat. 5 (oral)

Skin Corr./Irrit.: Cat. 2

Eye Dam./Irrit.: Cat. 1

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**4. First-Aid Measures**

General advice:

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:

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

Note to physician:

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

Treatment: Symptomatic treatment (decontamination, vital functions).

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**5. Fire-Fighting Measures**

Suitable extinguishing media:

water spray, foam, dry powder

Unsuitable extinguishing media for safety reasons:

water jet

Additional information:

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

Specific hazards:

carbon oxides, cyanides, nitrogen oxides

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

Special protective equipment:

Wear a self-contained breathing apparatus.

Further information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

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## 6. Accidental Release Measures

### Personal precautions:

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

### Environmental precautions:

Do not discharge into drains/surface waters/groundwater.

### Methods for cleaning up or taking up:

For small amounts: Contain with dust binding material and dispose of.

For large amounts: Sweep/shovel up.

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

Additional information: 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. Avoid dispersal of dust in the air (e.g. by clearing dusty surfaces with compressed air).

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## 7. Handling and Storage

### Handling

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

### Protection against fire and explosion:

The product is capable of dust explosion. Avoid dust formation. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy. Use explosion-proof apparatus and fittings.

### Storage

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

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## 8. Exposure controls and personal protection

### Components with occupational exposure limits

No substance specific occupational exposure limits known.

### 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 ISO 374-1) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN ISO 374-1): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) etc. 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. Wearing of closed work clothing is recommended. 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.

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## 9. Physical and Chemical Properties

|                           |  |                                     |
|---------------------------|--|-------------------------------------|
| Form:                     | powder   |                                     |
| Colour:                   | white to cream   |                                     |
| Odour:                    | almost odourless   |                                     |
| Odour threshold:          | not determined   |                                     |
| pH value:                 | 3 - 7<br>(100 g/l, 20 °C)                                    |                                     |
| melting range:            | >= 130 °C<br>The substance / product<br>decomposes.          |                                     |
| Boiling point:            | not applicable   |                                     |
| Flash point:              | not applicable   |                                     |
| Evaporation rate:         | negligible   |                                     |
| Flammability (solid/gas): | not highly flammable   | (VDI 2263, sheet 1, 1.2 (May 1990)) |
| Lower explosion limit:    | For solids not relevant for<br>classification and labelling. |                                     |
| Upper explosion limit:    | For solids not relevant for<br>classification and labelling. |                                     |
| Ignition temperature:     | approx. 420 °C   | (DIN 51794)                         |
| Thermal decomposition:    | > 165 °C   | (DSC (DIN 51007))                   |

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Explosion hazard: Product is not explosive, however a dust explosion could result from an air / dust mixture.

Fire promoting properties: not fire-propagating

Vapour pressure: negligible

Density: 1.2 g/cm<sup>3</sup>  
(20 °C)

Bulk density: 400 - 600 kg/m<sup>3</sup>

Solubility in water: > 800 g/l  
(23 °C)

Solubility (qualitative) solvent(s): organic solvents  
soluble

Partitioning coefficient n-octanol/water (log Pow): < -5

Viscosity, dynamic: not relevant

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## 10. Stability and Reactivity

Conditions to avoid:  
Avoid dust formation. Avoid electro-static charge. Avoid all sources of ignition: heat, sparks, open flame. See SDS section 7 - Handling and storage.

Thermal decomposition: > 165 °C (DSC (DIN 51007))

Substances to avoid:  
strong alkalis

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

Hazardous reactions:  
Dust explosion hazard.

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

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

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

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## 11. Toxicological Information

### Routes of exposure

**Acute oral toxicity**

Experimental/calculated data:  
LD50rat (oral): > 2,000 mg/kg (BASF-Test)

**Acute inhalation toxicity**

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

**Assessment of acute toxicity**

Virtually nontoxic after a single ingestion. Virtually nontoxic by inhalation.

**Symptoms**

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

**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:  
No data available.

**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.

**Developmental toxicity**

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

**Specific target organ toxicity (single exposure)**

Remarks: No data available.

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

Assessment of repeated dose toxicity:

No data available.

### **Aspiration hazard**

not applicable

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## **12. Ecological Information**

### **Ecotoxicity**

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)

### **Mobility**

Assessment transport between environmental compartments:

Adsorption to solid soil phase is not expected.

### **Persistence and degradability**

Elimination information:

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

### **Bioaccumulation potential**

Bioaccumulation potential:

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

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## **13. Disposal Considerations**

Observe national and local legal requirements.

Contaminated packaging:

Uncontaminated packaging can be re-used.

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

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## 14. Transport Information

### Domestic transport:

|                              |  |
|------------------------------|--|
|                              | Not classified as a dangerous good under transport regulations |
| UN number or ID 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   |

### Sea transport

#### IMDG

|                              |  |
|------------------------------|--|
|                              | Not classified as a dangerous good under transport regulations |
| UN number or ID number:      | Not applicable   |
| UN proper shipping name:     | Not applicable   |
| Transport hazard class(es):  | Not applicable   |
| Packing group:               | Not applicable   |
| Environmental hazards:       | Not applicable   |
|                              | Marine pollutant: no   |
| Special precautions for user | None known   |

### Air transport

#### IATA/ICAO

|                              |  |
|------------------------------|--|
|                              | Not classified as a dangerous good under transport regulations |
| UN number or ID number       | Not applicable   |
| 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   |

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## 15. Regulatory Information

### Other regulations

#### Registration status:

AICIS, AU



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Listed in AIIIC.

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## 16. Other Information

Any other intended applications should be discussed with the manufacturer. Corresponding occupational protection measurements must be followed.

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Vertical lines in the left hand margin indicate an amendment from the previous version.

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.