

# Safety data sheet

Page: 1/11

Safety data sheet according to the United Nations' Globally Harmonized System (UN GHS)

Date / Revised: 05.05.2025

Version: 1.0

Product: **Kollidon® 12 PF**

(ID no. 30034972/SDS\_GEN\_ZA/EN)

Date of print 21.10.2025

## 1. Identification

### Product identifier

### **Kollidon® 12 PF**

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:

### Emergency telephone number

National emergency number:

+27 11 203 2420

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

The product is under certain conditions capable of dust explosion.

---

## 3. Composition/Information on Ingredients

### Substances

#### Chemical nature

2-Pyrrolidinone, 1-ethenyl-, homopolymer  
CAS Number: 9003-39-8

#### Hazardous ingredients (GHS)

According to UN GHS criteria

Lactic acid

Content (W/W): > 0 % - < 0.2 %  
CAS Number: 50-21-5  
EC-Number: 200-018-0

Acute Tox. 5 (oral)  
Skin Irrit. 2  
Eye Dam. 1  
H318, H315, H303

For the classifications not written out in full in this section the full text can be found in section 16.

## 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:

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

### **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:

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.

### **Special hazards arising from the substance or mixture**

carbon oxides, cyanides, nitrogen oxides

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

### **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**

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).

**Personal precautions, protective equipment and emergency procedures**

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 and material for containment and cleaning 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.

---

## 7. Handling and Storage

**Precautions for safe 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.

**Conditions for safe storage, including any incompatibilities**

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

**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 substance specific occupational exposure limits known.

**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 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.

---

## 9. Physical and Chemical Properties

### 9.1. Information on basic physical and chemical properties

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

Solubility in water:

> 800 g/l  
(23 °C)

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

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

Vapour pressure:

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

Density:

## 9.2. Other information

### Information with regard to physical hazard classes

#### Explosives

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

#### Oxidizing properties

Fire promoting properties: not fire-propagating

#### Substances and mixtures, which emit flammable gases in contact with water

Formation of flammable gases:

Forms no flammable gases in the presence of water.

#### Corrosion to metals

Corrosive effects to metal are not anticipated.

### Other safety characteristics

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

SAPT-Temperature:

Study scientifically not justified.

Evaporation rate:

negligible

## 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:

flammable gases:

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

**Incompatible materials**

Substances to avoid:  
strong alkalis

**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:  
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

---

## 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 (H<sub>2</sub>O):**

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

Assessment transport between environmental compartments:

Adsorption in soil: Adsorption to solid soil phase is not 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 fulfill the criteria for PBT (Persistent/bioaccumulative/toxic) and vPvB (very persistent/very bioaccumulative). 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.

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 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

Safety data sheet according to the United Nations' Globally Harmonized System (UN GHS)

Date / Revised: 05.05.2025

Version: 1.0

Product: **Kollidon® 12 PF**

(ID no. 30034972/SDS\_GEN\_ZA/EN)

Date of print 21.10.2025

Special precautions for user      None known

**RID**

UN number or ID number: Not classified as a dangerous good under transport regulations  
 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****ADN**

UN number or ID number: Not classified as a dangerous good under transport regulations  
 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**

UN number or ID number: Not classified as a dangerous good under transport regulations  
 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**

UN number or ID number: Not classified as a dangerous good under transport regulations  
 UN proper shipping name: Not applicable  
 Transport hazard class(es): Not applicable  
 Packing group: Not applicable

---

Safety data sheet according to the United Nations' Globally Harmonized System (UN GHS)

Date / Revised: 05.05.2025

Version: 1.0

Product: **Kollidon® 12 PF**

(ID no. 30034972/SDS\_GEN\_ZA/EN)

Date of print 21.10.2025

Environmental hazards:	Not applicable
Special precautions for user	None known

**Maritime transport in bulk according to IMO instruments**

Maritime transport in bulk is not intended.

---

**15. Regulatory Information****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Not applicable

---

**16. Other Information**

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

Full text of classifications, hazard symbols and hazard statements, if mentioned in section 2 or 3:

Acute Tox.	Acute toxicity
Skin Irrit.	Skin irritation
Eye Dam.	Serious eye damage
H318	Causes serious eye damage.
H315	Causes skin irritation.
H303	May be harmful if swallowed.

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.