Safety data sheet

Safety data sheet according to the United Nations' Globally Harmonized System (UN GHS)
Date / Revised: 24.07.2024 Version: 2.0
Product: **Kollidon® 25**

(ID no. 30034967/SDS_GEN_ZA/EN)
Date of print 21.10.2025

1. Identification

Product identifier

Kollidon® 25
Chemical name: Polyvinylpyrrolidone
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

Formic acid

Content (W/W): > 0 % - < 1 %	Flam. Liq. 3
CAS Number: 64-18-6	Acute Tox. 3 (Inhalation - vapour)
EC-Number: 200-579-1	Acute Tox. 4 (oral)
INDEX-Number: 607-001-00-0	Skin Corr./Irrit. 1A
	Eye Dam./Irrit. 1
	H226, H314, H331, H302
	EUH071
	Specific concentration limit:
	Skin Corr./Irrit. 2: 2 - < 10 %
	Eye Dam./Irrit. 2: 2 - < 10 %
	Skin Corr./Irrit. 1A: >= 90 %
	Skin Corr./Irrit. 1B: 10 - < 90 %

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

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

Special hazards arising from the substance or mixture

cyanides, nitrogen oxides, carbon 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

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

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

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 raising dust.

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: Avoid extreme heat. Keep container tightly closed and dry.

Storage stability:
No specific storage temperature specified.

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

64-18-6: Formic acid
STEL value 20 ppm

TWA value 10 ppm

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 P1or FFP1)

Hand protection:
Chemical resistant protective gloves (EN ISO 374-1)

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
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:	dropped	
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, the product is a solid	
Thermal decomposition:	225 °C (DSC (DIN 51007))	
SADT:	Not a substance liable to self-decomposition according to UN transport regulations, class 4.1.	

pH value: 3.0 - 5.0

Viscosity, dynamic:
not relevant

Solubility in water: fully soluble

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

Partitioning coefficient n-octanol/water (log Kow):
No data available.

Vapour pressure:
negligible

Density:
No information is available for the absolute density. Instead the bulk density was determined as a more relevant value.

Relative vapour density (air):
The product is a non-volatile solid.

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

Flammable solids

Burning rate:	The material doesn't meet the criteria specified in paragraph 33.2.4.4 of UN manual of tests and criteria. An ignition of the test substance does not lead to a progagation by burning with flame or smouldering.	(UN Test N.1 (ready combustible solids))

Self-heating substances and mixtures

Self heating ability:	It is not a substance capable of spontaneous heating according to UN transport regulations class 4.2.	(VDI 2263, sheet 1, 1.4.1 (May 1990))

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

Minimum ignition energy:
The product is capable of dust explosion.

Bulk density: 400 - 490 kg/m3

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 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. 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 alkalies

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 (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

Assessment transport between environmental compartments:
Adsorption in soil: No data available.

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
Special precautions for user	None known

RID

	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

Inland waterway transport

ADN

	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

Transport in inland waterway vessel
Not evaluated

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
Special precautions for	None known

user

Air transport

IATA/ICAO

	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

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:

Flam. Liq.	Flammable liquids
Acute Tox.	Acute toxicity
Skin Corr./Irrit.	Skin corrosion/irritation
Eye Dam./Irrit.	Serious eye damage/eye irritation
H226	Flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
H331	Toxic if inhaled.
H302	Harmful if swallowed.
EUH071	Corrosive to the respiratory tract.

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.