

Safety data sheet

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BASF Safety data sheet
Date / Revised: 29.07.2024
Product: **Kollidon® 25**

Version: 6.1

(30034967/SDS_GEN_AU/EN)

Date of print: 12.10.2025

1. Substance/preparation and manufacturer/supplier identification

Product name:
Kollidon® 25

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
CAS Number: 9003-39-8

Hazardous ingredients

formic acid

Content (W/W): > 0 % - < 1 %
CAS Number: 64-18-6

Flam. Liq.: Cat. 3
Acute Tox.: Cat. 3 (Inhalation - vapour)
Acute Tox.: Cat. 4 (oral)
Skin Corr./Irrit.: Cat. 1A
Eye Dam./Irrit.: Cat. 1

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).

5. Fire-Fighting Measures

Suitable extinguishing media:

water spray, foam, dry powder

Additional information:

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

Specific hazards:

cyanides, nitrogen oxides, carbon oxides

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

Special protective equipment:

Wear a self-contained breathing apparatus.

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Further information:

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

6. Accidental Release Measures

Personal precautions:

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 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 raising dust.

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).

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

Storage stability:

No specific storage temperature specified.

8. Exposure controls and personal protection

Components with occupational exposure limits

formic acid, 64-18-6;

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TWA value 5 ppm (ACGIHTLV)
STEL value 10 ppm (ACGIHTLV)
TWA value 9.4 mg/m³ ; 5 ppm (AU NOEL)
STEL value 19 mg/m³ ; 10 ppm (AU NOEL)
TWA value 9.4 mg/m³ ; 5 ppm (OEL (AU))
STEL value 19 mg/m³ ; 10 ppm (OEL (AU))

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:

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

Form:	powder
Colour:	white to cream
Odour:	almost odourless
Odour threshold:	not determined
pH value:	3.0 - 5.0
melting range:	>= 130 °C The substance / product decomposes.
Boiling point:	dropped
Flash point:	
Evaporation rate:	not applicable, the product is a solid negligible

Flammability (solid/gas): not highly flammable

(VDI 2263, sheet 1, 1.2 (May 1990))

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Lower explosion limit:	For solids not relevant for classification and labelling.
Upper explosion limit:	For solids not relevant for classification and labelling.
Thermal decomposition:	225 °C (DSC (DIN 51007))
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))
SADT:	Not a substance liable to self-decomposition according to UN transport regulations, class 4.1.
Minimum ignition energy:	The product is capable of dust explosion.
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:	No information is available for the absolute density. Instead the bulk density was determined as a more relevant value.
Bulk density:	400 - 490 kg/m ³
Relative vapour density (air):	The product is a non-volatile solid.
Solubility in water:	fully soluble
Solubility (qualitative) solvent(s):	organic solvents soluble
Partitioning coefficient n-octanol/water (log Pow):	No data available.
Viscosity, dynamic:	not relevant

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: 225 °C (DSC (DIN 51007))

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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.

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

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:

No data available.

Persistence and degradability

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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.

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.

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

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Environmental hazards:	Not applicable
Special precautions for user	None known

15. Regulatory Information

Other regulations

Registration status:

AICIS, AU

Listed in AICC.

16. Other Information

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

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.