

Safety data sheet

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BASF safety data sheet. This is a translation of the country-specific safety data sheet into a language other than that required by law. This document does not replace the safety data sheet provided according to Regulation (EC) No 1907/2006.

Date / Revised: 10.10.2022

Version: 2.0

Date previous version: 25.03.2022

Previous version: 1.1

Date / First version: 14.02.2022

Product: **Kollidon® 25**

(ID no. 30034967/SDS_GEN_IT/EN)

Date of print 21.10.2025

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Kollidon® 25

Chemical name: Polyvinylpyrrolidone

CAS Number: 9003-39-8

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: pharmaceutical excipient

1.3. Details of the supplier of the safety data sheet

Company:

BASF SE
67056 Ludwigshafen
GERMANY

Contact address:

BASF Italia S.p.A.
Via Marconato 8
20811 Cesano Maderno (MB)
ITALY

Telephone: +39 0362 512-1

E-mail address: Sicurezzaprodotti.BASF-Italia@basf.com

1.4. Emergency telephone number

International emergency number:

Telephone: +49 180 2273-112

CAV "Osp. Pediatrico Bambino Gesù"

Az. Osp. Univ. Foggia

Az. Osp. "A. Cardarelli"

CAV Policlinico "Umberto I"

CAV Policlinico "A. Gemelli"

Az. Osp. "Careggi" U.O. Tossicologia Medica

Roma 06 68593726

Foggia 800183459

Napoli 081-5453333

Roma 06-49978000

Roma 06-3054343

Firenze 055-7947819

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CAV Centro Nazionale di Informazione Tossicologica Pavia	0382-24444
Osp. Niguarda Ca' Granda	Milano 02-66101029
Azienda Ospedaliera Papa Giovanni XXII	Bergamo 800883300
Azienda Ospedaliera Integrata Verona	Verona 800011858

SECTION 2: Hazards Identification

2.1. 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.

2.2. Label elements

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

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

2.3. Other hazards

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

The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

The product is under certain conditions capable of dust explosion.

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Chemical nature

2-Pyrrolidinone, 1-ethenyl-, homopolymer

CAS Number: 9003-39-8

3.2. Mixtures

Not applicable

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SECTION 4: First-Aid Measures

4.1. 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.

4.2. Most important symptoms and effects, both acute and delayed

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

4.3. Indication of any immediate medical attention and special treatment needed

Treatment: Symptomatic treatment (decontamination, vital functions).

SECTION 5: Fire-Fighting Measures

5.1. 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.

5.2. Special hazards arising from the substance or mixture

Endangering substances: cyanides, nitrogen oxides, carbon oxides

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

5.3. 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.

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SECTION 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).

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Do not discharge into drains/surface waters/groundwater.

6.3. 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.

6.4. Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

SECTION 7: Handling and Storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. 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.

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SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Components with occupational exposure limits

No substance specific occupational exposure limits known.

8.2. 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:

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.

SECTION 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:	$\geq 130\text{ °C}$
	The substance / product decomposes.
Boiling point:	
	dropped
Flammability:	not highly flammable

(VDI 2263, sheet 1, 1.2)

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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.

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

Relative vapour density (air):

The product is a non-volatile solid.

Particle characteristics

No data available. -

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: 200 mm (Directive 92/69/EEC, A.10)
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 propagation by burning with flame or smouldering.

Self-heating substances and mixtures

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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)

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: 10 - 30 mJ (VDI 2263, sheet 1, 2.5)
(1.013 hPa, 20 °C)

Inductivity: 1 mH

The product is capable of dust explosion.

Bulk density: 400 - 490 kg/m³

SAPT-Temperature:

Study scientifically not justified.

Evaporation rate:

negligible

SECTION 10: Stability and Reactivity

10.1. 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.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Dust explosion hazard.

10.4. 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.

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10.5. Incompatible materials

Substances to avoid:
strong alkalis

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

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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

Interactive effects

No data available.

11.2. Information on other hazards

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Endocrine disrupting properties

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological Information

12.1. 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)

12.2. 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.

12.3. Bioaccumulative potential

Bioaccumulation potential:

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

12.4. Mobility in soil

Assessment transport between environmental compartments:

Adsorption in soil: No data available.

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12.5. 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 contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self classification

12.6. Endocrine disrupting properties

Product does not contain a substance above legal limits included in the list established in accordance with Article 59(1) of Regulation (EC) No 1907/2006 for having endocrine disrupting properties or is identified to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

SECTION 13: Disposal Considerations

13.1. 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.

SECTION 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

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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 user	None known

Air transport

IATA/ICAO

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

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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

14.1. UN number or ID number

See corresponding entries for "UN number or ID number" for the respective regulations in the tables above.

14.2. UN proper shipping name

See corresponding entries for "UN proper shipping name" for the respective regulations in the tables above.

14.3. Transport hazard class(es)

See corresponding entries for "Transport hazard class(es)" for the respective regulations in the tables above.

14.4. Packing group

See corresponding entries for "Packing group" for the respective regulations in the tables above.

14.5. Environmental hazards

See corresponding entries for "Environmental hazards" for the respective regulations in the tables above.

14.6. Special precautions for user

See corresponding entries for "Special precautions for user" for the respective regulations in the tables above.

14.7. Maritime transport in bulk according to IMO instruments

Maritime transport in bulk is not intended.

SECTION 15: Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibitions, Restrictions and Authorizations

Annex XVII of Regulation (EC) No 1907/2006: Number on List: 75

Directive 2012/18/EU - Control of Major Accident Hazards involving dangerous substances (EU):
Listed in above regulation: no

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Regulations (Italy): 1) 1272/2008/CE Regulation and subsequent amendments; 2) 2012/18/EU Directive (Seveso III) and Legislative Decree 105/2015; 3) Legislative Decree 81/2008 and Legislative Decree 152/2006.

15.2. Chemical Safety Assessment

Chemical Safety Assessment not required

SECTION 16: Other Information

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

Abbreviations

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road.
ADN = The European Agreement concerning the International Carriage of Dangerous Goods by Inland waterways. ATE = Acute Toxicity Estimates. CAO = Cargo Aircraft Only. CAS = Chemical Abstract Service. CLP = Classification, Labelling and Packaging of substances and mixtures. DIN = German national organization for standardization. DNEL = Derived No Effect Level. EC50 = Effective concentration median for 50% of the population. EC = European Community. EN = European Standards. IARC = International Agency for Research on Cancer. IATA = International Air Transport Association. IBC-Code = Intermediate Bulk Container code. IMDG = International Maritime Dangerous Goods Code. ISO = International Organization for Standardization. STEL = Short-Term Exposure Limit. LC50 = Lethal concentration median for 50% of the population. LD50 = Lethal dose median for 50% of the population. TLV = Threshold Limit Value. MARPOL = The International Convention for the Prevention of Pollution from Ships. NEN = Dutch Norm. NOEC = No Observed Effect Concentration. OEL = Occupational Exposure Limit. OECD = Organization for Economic Cooperation and Development. PBT = Persistent, Bioaccumulative and Toxic. PNEC = Predicted No Effect Level. PPM = Parts per million. RID = The European Agreement concerning the International Carriage of Dangerous Goods by Rail. TWA = Time Weight Average. UN-number = UN number at transport. vPvB = very Persistent and very Bioaccumulative.

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.