

Safety Data Sheet

Kollidon® 25

Revision date : 2025/08/18

Version: 8.0

Page: 1/10

(30034967/SDS_GEN_US/EN)

1. Identification

Product identifier used on the label

Kollidon® 25

Recommended use of the chemical and restriction on use

Recommended use*: pharmaceutical excipient

Unsuitable for use: Not intended for sale to or use by the general public.

* The "Recommended use" identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:

BASF CORPORATION
100 Park Avenue
Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

Emergency telephone number

24 Hour Emergency Response Information

CHEMTREC: 1-800-424-9300

BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

Synonyms: Polyvinylpyrrolidone

2. Hazards Identification

According to Regulation 2024 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Classification of the product

Combustible Dust

Combustible Dust (1)

Combustible Dust

Label elements

Signal Word:

Warning

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18
Version: 8.0

Page: 2/10
(30034967/SDS_GEN_US/EN)

Hazard Statement:

May form combustible dust concentration in air.

Hazards not otherwise classified

The product is under certain conditions capable of dust explosion.

3. Composition / Information on Ingredients

According to Regulation 2024 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Under the referenced regulation, this product does not contain any components classified for health hazards above the relevant cut off value.

4. First-Aid Measures

Description of first aid measures

General advice:

Remove contaminated clothing.

If inhaled:

Keep patient calm, remove to fresh air.

If on skin:

Wash thoroughly with soap and water

If in eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open.

If swallowed:

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

Most important symptoms and effects, both acute and delayed

Symptoms: No applicable information available.

Indication of any immediate medical attention and special treatment needed

Note to physician

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Extinguishing media

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18
Version: 8.0

Page: 3/10
(30034967/SDS_GEN_US/EN)

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

Hazards during fire-fighting:
cyanides, nitrogen oxides, carbon oxides
The substances/groups of substances mentioned can be released in case of fire.

Dust explosion hazard.

Advice for fire-fighters

Protective equipment for fire-fighting:
Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.

Further information:

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

Dusty conditions may ignite explosively in the presence of an ignition source causing flash fire.

6. Accidental release measures

Further 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

Wear appropriate respiratory protection. Use personal protective clothing. Ensure adequate ventilation.

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.

Nonsparking tools should be used.

7. Handling and Storage

Precautions for safe handling

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

Protection against fire and explosion:

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18

Version: 8.0

Page: 4/10

(30034967/SDS_GEN_US/EN)

Avoid dust formation. 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. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Refer to NFPA 660 (2025) Standard for Combustible Dust and Particulate Solids. NFPA 660 is a combination of Standards NFPA 61 (Agriculture and Food), NFPA 484 (Metals), NFPA 652 (Fundamentals of Combustible Dusts), NFPA 654 (Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids), NFPA 65 (Sulfur), and NFPA 664 (Woodworking/Processing). Consult NFPA 660 standard for relevant commodity-specific and general safety information.

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.

8. Exposure Controls/Personal Protection

Components with occupational exposure limits

Formic Acid	ACGIH, US:	TWA value 5 ppm ;
	OSHA Z1:	PEL 5 ppm 9 mg/m3 ;
	NIO ID, US:	IDLH 30 ppm ; IDLH values based on the 1994 Revised Criteria
	NIO ID, US:	LEL 18 % ;

Advice on system design:

Provide local exhaust ventilation to control dusts/mists. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection:

Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator as needed.

Hand protection:

Chemical resistant protective gloves

Eye protection:

Safety glasses with side-shields.

Body protection:

Body protection must be chosen based on level of activity and exposure.

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18

Version: 8.0

Page: 5/10

(30034967/SDS_GEN_US/EN)

General safety and hygiene measures:

Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Wear protective clothing as necessary to minimize contact. 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

Physical state:	solid
Form:	powder
Odour:	almost odourless
Odour threshold:	not determined
Colour:	white to cream
pH value:	3.0 - 5.0
melting range:	≥ 130 °C The substance / product decomposes.
freezing range:	No data available.
Boiling point:	dropped
Flash point:	not applicable, the product is a solid
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.
SADT:	Not a substance liable to self-decomposition according to UN transport regulations, class 4.1.
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:	The product is a non-volatile solid.
Partitioning coefficient n-octanol/water (log Pow):	No data available.
Thermal decomposition:	225 °C (DSC (DIN 51007))
Viscosity, dynamic:	not relevant
Viscosity, kinematic:	No data available.
Solubility in water:	fully soluble
Solubility (qualitative):	soluble
	solvent(s): organic solvents,
Molecular weight:	No data available.
Evaporation rate:	negligible

Particle characteristics

Particle size distribution: typically > 30 µm (D50, Volumetric Distribution, ISO 13320-1)

10. Stability and Reactivity

Reactivity

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

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18
Version: 8.0

Page: 6/10
(30034967/SDS_GEN_US/EN)

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

Oxidizing properties:
not fire-propagating

Minimum ignition energy:

The product is capable of dust explosion.

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 discharge. Avoid all sources of ignition: heat, sparks, open flame.

Incompatible materials

strong alkalis

Hazardous decomposition products

Decomposition products:

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

Thermal decomposition:

225 °C (DSC (DIN 51007))

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Virtually nontoxic after a single ingestion. Virtually nontoxic by inhalation.

Oral

Type of value: LD50

Species: rat

Value: > 2,000 mg/kg (BASF-Test)

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18
Version: 8.0

Page: 7/10
(30034967/SDS_GEN_US/EN)

Inhalation

Type of value: LC50

Species: rat

Value: > 5.2 mg/l (OECD Guideline 403)

Exposure time: 4 h

Dermal

No data available.

Assessment other acute effects

No data available.

Irritation / corrosion

Assessment of irritating effects: Not irritating to the skin. Not irritating to the eyes.

Skin

Species: rabbit

Result: non-irritant

Method: Draize test

Eye

Species: rabbit

Result: non-irritant

Method: Draize test

Sensitization

Assessment of sensitization: No data available.

Aspiration Hazard

not applicable

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: No data available.

Genetic toxicity

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.

Reproduction

Experimental/calculated data: No data available.

Teratogenicity

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

12. Ecological Information

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18
Version: 8.0

Page: 8/10
(30034967/SDS_GEN_US/EN)

Toxicity

Aquatic 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

Toxicity to microorganisms

OECD Guideline 209 aerobic

activated sludge, industrial/EC20 (0.5 h): > 1,995 mg/l

Persistence and degradability

Assessment biodegradation and elimination (H2O)

Poorly eliminated from water.

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

No data available.

Additional information

Other ecotoxicological advice:

No data available.

13. Disposal considerations

Waste disposal of substance:

Do not discharge into drains/surface waters/groundwater. Dispose of in accordance with national, state and local regulations.

Container disposal:

Uncontaminated packaging can be re-used. Packs that cannot be cleaned should be disposed of in the same manner as the contents.

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18
Version: 8.0

Page: 9/10
(30034967/SDS_GEN_US/EN)

14. Transport Information

Land transport
USDOT

Not classified as a dangerous good under transport regulations

Sea transport
IMDG

Not classified as a dangerous good under transport regulations

Air transport
IATA/ICAO

Not classified as a dangerous good under transport regulations

15. Regulatory Information

Federal Regulations

Registration status:

Pharma TSCA, US released / exempt

Chemical TSCA, US released / listed

Chemical TSCA, US

All substances are TSCA listed and active.

EPCRA 311/312 (Hazard categories): Refer to SDS section 2 for GHS hazard classes applicable for this product.

State regulations

State RTK
PA

CAS Number
616-45-5

Chemical name
2-Pyrrolidone

Safe Drinking Water & Toxic Enforcement Act, CA Prop. 65:

WARNING: This product can expose you to chemicals including ACETALDEHYDE, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

NFPA Hazard codes:

Health: 0 Fire: 1 Reactivity: 0 Special:

HMIS III rating

Health: 0 Flammability: 1 Physical hazard: 0

16. Other Information

SDS Prepared by:

BASF NA Product Regulations

Safety Data Sheet

Kollidon® 25

Revision date: 2025/08/18

Version: 8.0

Page: 10/10

(30034967/SDS_GEN_US/EN)

SDS Prepared on: 2025/08/18

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END OF DATA SHEET