

Safety Data Sheet

Kollidon® CL

Revision date : 2025/08/13

Version: 5.0

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(30034964/SDS_GEN_MX/EN)

1. Identification

Product identifier used on the label

Kollidon® CL

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 Mexicana S.A. de C.V.
Av. Insurgentes Sur 975
Col. CD. De Los Deportes,
C.P. 03710 Ciudad de México
MÉXICO

Telephone: +52 55 5325 2600

Emergency telephone number

24 Hour Emergency Response Information

SETIQ: 1800-00-214-(Rep. Mexicana) or 55-59-15-88 (CDMX)

Telephone: +1-800-849-5204 or +1-833-229-1000

Other means of identification

Synonyms: 2-Pyrrolidinone, 1-ethenyl-, homopolymer

2. Hazards Identification

According to Regulation NOM-018-STPS-2015

Classification of the product

Combustible Dust

Combustible Dust (1)

Combustible Dust

Label elements

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Signal Word:
Warning

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 NOM-018-STPS-2015

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. Assist in breathing if necessary. Seek medical attention.

If on skin:
Wash affected areas thoroughly with soap and water. If irritation develops, seek medical attention.

If in eyes:
In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. If irritation develops, seek medical attention.

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

Most important symptoms and effects, both acute and delayed

Symptoms: No data available.

Indication of any immediate medical attention and special treatment needed

Note to physician

Treatment: Symptomatic treatment (decontamination, vital functions).

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5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:
water spray, foam, dry powder, carbon dioxide

Unsuitable extinguishing media for safety reasons:
water jet

Special hazards arising from the substance or mixture

Hazards during fire-fighting:
hydrogen cyanide, carbon oxides, nitrogen oxides, harmful vapours
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 dispersal of dust in the air (e.g. by clearing dusty surfaces with compressed air). 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.

Personal precautions, protective equipment and emergency procedures

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

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

Handle in accordance with good industrial hygiene and safety practice. Avoid dust formation. Provide exhaust ventilation if dust is formed.

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Protection against fire and explosion:

Avoid whirling up the material/product because of the 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. 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.

Dust explosion class: Dust explosion class 2 (Kst-value 200 up to 300 bar m s-1).

Conditions for safe storage, including any incompatibilities

Suitable materials for containers: High density polyethylene (HDPE), Low density polyethylene (LDPE), Stainless steel 1.4301 (V2), Stainless steel 1.4401, glass, tinned carbon steel (Tinplate), Aluminium

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

8. Exposure Controls/Personal Protection

No substance specific occupational exposure limits known.

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:

Wear safety goggles (chemical goggles) if there is potential for airborne dust exposures.

Body protection:

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

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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:	5 - 7 (1 %(m), 20 °C) (as aqueous suspension)	
melting range:	>= 130 °C The substance / product decomposes.	
freezing range:	No data available.	
Boiling point:	not applicable	
Flash point:	not applicable, the product is a solid	
Flammability:	not highly flammable	(VDI 2263, sheet 1, 1.1 (May 1990))
Lower explosion limit:	For solids not relevant for classification and labelling.	
Upper explosion limit:	For solids not relevant for classification and labelling.	
Vapour pressure:	dropped	
Density:	No information is available for the absolute density. Instead the bulk density was determined as a more relevant value.	
Bulk density:	approx. 330 kg/m ³	
Relative vapour density:	not relevant	
Partitioning coefficient n-octanol/water (log Pow):	not determined	
Thermal decomposition:	150 °C (DSC (DIN 51007))	
Viscosity, dynamic:	not applicable, the product is a solid	
Viscosity, kinematic:	No data available.	
Solubility in water:	insoluble	
Solubility (qualitative):	insoluble	
	solvent(s): organic solvents,	
Molecular weight:	No data available.	
Evaporation rate:	The product is a non-volatile solid.	
<u>Particle characteristics</u>		
Particle size distribution:	typically > 50 µm	(D50, Volumetric Distribution, ISO 13320-1)

10. Stability and Reactivity

Reactivity

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

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

Oxidizing properties:
not fire-propagating

Dust explosivity characteristics:
Kst: 205 m.bar/s (VDI 2263)

Dust explosion class:
Dust explosion class 2 (Kst-value 200 up to 300 bar m s-1) (St 2)
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

strong alkalis

Hazardous decomposition products

Thermal decomposition:
150 °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)

Inhalation

Type of value: LC50

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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.

Teratogenicity

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

12. Ecological Information

Toxicity

Aquatic toxicity
Assessment of aquatic toxicity:

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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)

Assessment of terrestrial toxicity

No data available.

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:

Observe national and local legal requirements.

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

Container disposal:

Dispose of in a licensed facility. Recommend crushing, puncturing or other means to prevent unauthorized use of used containers.

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14. Transport Information

Land transport

TDG

Hazard class: 4.2
Packing group: III
ID number: UN 3088
Hazard label: 4.2
Proper shipping name: SELF-HEATING SOLID, ORGANIC, N.O.S. (contains 1-ETHENYL-2-PYRROLIDINONE, HOMOPOLYMER)

Sea transport

IMDG

Hazard class: 4.2
Packing group: III
ID number: UN 3088
Hazard label: 4.2
Marine pollutant: NO
Proper shipping name: SELF-HEATING SOLID, ORGANIC, N.O.S. (contains 1-ETHENYL-2-PYRROLIDINONE, HOMOPOLYMER)

Air transport

IATA/ICAO

Hazard class: 4.2
Packing group: III
ID number: UN 3088
Hazard label: 4.2
Proper shipping name: SELF-HEATING SOLID, ORGANIC, N.O.S. (contains 1-ETHENYL-2-PYRROLIDINONE, HOMOPOLYMER)

15. Regulatory Information

Federal Regulations

Not applicable

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

SDS Prepared on: 2025/08/13

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This information is considered accurate but is not exhaustive and shall only be used as a guideline based on current knowledge of the chemical substance or mixture. Safety precautions suitable for the product must be applied.

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