We create chemistry

# Safety data sheet



## 1. Substance/preparation and manufacturer/supplier identification

**Product name:**
Kollidon® CL

Use: pharmaceutical excipient

Manufacturer/supplier:
BASF (Thai) Limited
23rd Floor, Emporium Tower, 622, Sukhumvit 24 Rd.,
Klongton, Klongtoey, Bangkok 10110, THAILAND
Telephone: +66 2624-1999
Telefax number: +66 2664-9254
E-mail address: Thailand-SDS-info@basf.com

Emergency information:
International emergency number:
Telephone: +49 180 2273-112

## 2. Hazard identification

**Classification according to UN GHS 2009**

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

Substance nature: Substance

2-Pyrrolidinone, 1-ethenyl-, homopolymer
CAS Number: 9003-39-8

crosslinked, Microgranule (MG)

No particular hazards known.

## 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, carbon dioxide

Unsuitable extinguishing media for safety reasons:
water jet

Specific hazards:
hydrogen cyanide, carbon oxides, nitrogen oxides, harmful vapours
The substances/groups of substances mentioned can be released in case of fire. Dust explosion hazard.

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

Personal precautions:
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 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

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

Protection against fire and explosion:
Avoid dust formation. The product is capable of dust explosion. Take precautionary measures against static discharges. Avoid all sources of ignition: heat, sparks, open flame. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

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

Storage

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

## 8. Exposure controls and personal protection

Components with occupational exposure limits

No substance specific occupational exposure limits known.

Personal protective equipment

Respiratory protection:
Breathing protection if dusts are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1or FFP1)

Hand protection:
Wear chemical resistant protective gloves.

Eye protection:
Safety glasses with side-shields (frame goggles) (e.g. EN 166)

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

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: | 5 - 7<br>(1 %(m), 20 °C)<br>(as aqueous suspension) | |
| melting range: | >= 130 °C<br>The substance / product decomposes. | |
| Boiling point: | not applicable | |
| Flash point: | not applicable, the product is a solid | |
| Evaporation rate: | The product is a non-volatile solid. | |
| Flammability (solid/gas): | 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. | |
| Thermal decomposition: | 150 °C | (DSC (DIN 51007)) |

| | | |
|---|---|---|
| Self heating ability: | It is a substance capable of spontaneous heating according to UN transport regulations class 4.2. Based on test results packaging < 450 l are exempted from the classification. | (UN Test N.4 (self heating substances)) |
| 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:
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/m3

Relative vapour density (air):
not relevant

Solubility in water: insoluble

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

Partitioning coefficient n-octanol/water (log Pow):
not determined

Viscosity, dynamic:
not applicable, the product is a solid

## 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: 150 °C (DSC (DIN 51007))

Substances to avoid:
strong alkalies

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

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:**

| | |
|---|---|
| UN number or ID number: | UN 3088 |
| UN proper shipping name: | SELF-HEATING SOLID, ORGANIC, N.O.S. (1-ETHENYL-2-PYRROLIDINONE, HOMOPOLYMER) |
| Transport hazard class(es): | 4.2 |
| Packing group: | III |
| Environmental hazards: | no |
| Special precautions for user: | Not dangerous goods of class 4.2 in packages up to 450 litres capacity. |

**Sea transport**
IMDG

| | |
|---|---|
| UN number or ID number: | UN 3088 |
| UN proper shipping name: | SELF-HEATING SOLID, ORGANIC, N.O.S. (1-ETHENYL-2-PYRROLIDINONE, HOMOPOLYMER) |
| Transport hazard class(es): | 4.2 |
| Packing group: | III |
| Environmental hazards: | no<br>Marine pollutant: NO |
| Special precautions for user: | EmS: F-A; S-J<br>Not dangerous goods of class 4.2 in packages up to 450 litres capacity. |

**Air transport**
IATA/ICAO

| | |
|---|---|
| UN number or ID number: | UN 3088 |
| UN proper shipping name: | SELF-HEATING SOLID, ORGANIC, N.O.S. (1-ETHENYL-2-PYRROLIDINONE, HOMOPOLYMER) |
| Transport hazard class(es): | 4.2 |
| Packing group: | III |
| Environmental hazards: | No Mark as dangerous for the environment is needed |
| Special precautions for user: | Not dangerous goods of class 4.2 in packages up to 450 litres capacity. |

### Maritime transport in bulk according to IMO instruments

Maritime transport in bulk is not intended.

## 15. Regulatory Information

**Other regulations**

## 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.