

Safety data sheet

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BASF Safety data sheet

Date / Revised: 09.08.2024 Version: 6.2

Product: Kollidon® 90 F

(30034978/SDS_GEN_AU/EN)

Date of print: 11.10.2025

1. Substance/preparation and manufacturer/supplier identification

Product name:

Kollidon® 90 F

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 % Flam. Liq.: Cat. 3

CAS Number: 64-18-6 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

Hazards: No hazards anticipated.

Treatment: Symptomatic treatment (decontamination, vital functions).

5. Fire-Fighting Measures

Suitable extinguishing media: foam, water spray, dry powder

Specific hazards:

harmful vapours, carbon oxides, nitrogen oxides

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.

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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:

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

Environmental precautions:

Do not discharge into drains/surface waters/groundwater.

Methods for cleaning up or taking up:

For small amounts: Pick up with suitable appliance 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.

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: Containers should be stored tightly sealed in a dry place. Protect against heat.

Storage stability:

No specific storage temperature necessary.

8. Exposure controls and personal protection

Components with occupational exposure limits

formic acid, 64-18-6;

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))

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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 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: 5.0 - 9.0 (Ph. Eur. 2.2.3)

(water, 10 %(m), 20 °C)

melting range: >= 130 °C

The substance / product

decomposes.

Boiling point:

The product is a non-volatile solid.

Flash point:

not applicable

Evaporation rate:

The product is a non-volatile solid.

Flammability (solid/gas): not highly flammable (other) Lower explosion limit: 50 g/m3 (air)

For solids not relevant for

classification and labelling.

Upper explosion limit:

For solids not relevant for

classification and labelling.

Ignition temperature: 425 °C (DIN 51794)

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Thermal decomposition: 425 °C (DSC (DIN 51007))

It is not a self-decompositionable

substance.

Self ignition: not self-igniting

Self heating ability: It is a substance capable of (UN Test N.4 (self heating

spontaneous heating according to substances))

UN transport regulations class 4.2. Based on test results packaging <

3m3 are exempted from the

classification.

SADT: Not a substance liable to self-decomposition according to UN transport

regulations, class 4.1.

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:

not applicable

Density: 1.2 g/cm3

(20 °C)

Relative density:

No data available.

Bulk density: approx. 400 - 600 kg/m3 (DIN EN ISO 60)

Relative vapour density (air):

The product is a non-volatile solid.

Solubility in water:

> 270 g/l (23 °C)

Miscibility with water:

soluble

Solubility (qualitative) solvent(s): organic solvents

soluble

Partitioning coefficient n-octanol/water (log Pow):

not determined

Information on: Polyvinylpyrrolidone

Partitioning coefficient n-octanol/water (log Pow): -3.4

Viscosity, dynamic: 10,000 - 30,000 mPa.s (DIN EN ISO 2555 (RVT))

(20 %(m), 23 °C)

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: 425 °C (DSC (DIN 51007))

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It is not a self-decompositionable substance.

Substances to avoid:

No substances known that should be avoided.

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 eyes and skin.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (Draize test)

Serious eye damage/irritation rabbit: non-irritant (Draize test)

Germ cell mutagenicity

Assessment of mutagenicity:

The substance was not mutagenic in studies with mammals.

Carcinogenicity

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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:

Not expected to cause reproductive toxicity (based on composition).

Developmental toxicity

Assessment of teratogenicity:

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

Specific target organ toxicity (single exposure)

Based on the available information there is no specific target organ toxicity to be expected after a single exposure.

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

None known

Aspiration hazard

No aspiration hazard expected.

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

Assessment biodegradation and elimination (H2O):

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Poorly eliminated from water.

Information on: 2-Pyrrolidinone, 1-ethenyl-, homopolymer

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.

Additional information

Other ecotoxicological advice:

Ecological data are determined by analogy.

13. Disposal Considerations

Must be sent to a suitable incineration plant, observing local regulations.

A waste code in accordance with the European waste catalog (EWC) cannot be specified, due to dependence on the usage.

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

Not dangerous goods of class 4.2 in packages up to 3000 litres

user: capacity.

Further information

Hazchem Code:1Y IERG Number:23

Sea transport

IMDG

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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

Marine pollutant: NO

Special precautions for EmS: F-A; S-J

user: Not dangerous goods of class 4.2 in packages up to 3000 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 Not dangerous goods of class 4.2 in packages up to 3000 litres

user: capacity.

Further information

Not dangerous goods of class 4.2 in packages up to 3000 litres capacity.

15. Regulatory Information

Other regulations

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP): Not Scheduled

Registration status:

AICIS, AU

Listed in AIIC.

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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.

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