1. Identification

Product identifier used on the label

Kollidon® 25

Recommended use of the chemical and restriction on use

Recommended use*: pharmaceutical excipient

* 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

CHEMTREC: 1-800-424-9300
BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

Synonyms: Polyvinylpyrrolidone

2. Hazards Identification


Classification of the product

Combustible Dust  Combustible Dust (1)  Combustible Dust

Label elements

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. The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria.

3. Composition / Information on Ingredients


<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Weight %</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>616-45-5</td>
<td>1.0 - 3.0%</td>
<td>2-Pyrrolidone</td>
</tr>
</tbody>
</table>

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 necessary.

**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 plenty of water. Seek medical attention if necessary.

**Most important symptoms and effects, both acute and delayed**

Symptoms: No significant symptoms are expected due to the non-classification of the product.

**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**

Suitable extinguishing media:
water spray, foam, dry powder
Special hazards arising from the substance or mixture
Hazards during fire-fighting:
carbon dioxide, cyanides, nitrogen 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. Avoid dispersal of dust in the air (i.e., clearing dust 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: Sweep/shovel up.
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. Keep container tightly sealed.

Protection against fire and explosion:
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 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids (2013 Edition) for safe handling.

Conditions for safe storage, including any incompatibilities
Further information on storage conditions: Avoid extreme heat. Keep container tightly closed and dry.
8. Exposure Controls/Personal Protection

No 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:
Safety glasses with side-shields.

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. Wear protective clothing as necessary to minimize contact. Hands and/or face should be washed before breaks and at the end of the shift.

9. Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>powder</td>
</tr>
<tr>
<td>Odour</td>
<td>faint specific odour</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>not determined</td>
</tr>
<tr>
<td>Colour</td>
<td>white to cream</td>
</tr>
<tr>
<td>pH value</td>
<td>3.0 - 5.0</td>
</tr>
<tr>
<td>Melting range</td>
<td>&gt;= 130 °C</td>
</tr>
<tr>
<td>Boiling point</td>
<td>dropped</td>
</tr>
<tr>
<td>Flash point</td>
<td>not applicable</td>
</tr>
<tr>
<td>Flammability</td>
<td>not highly flammable</td>
</tr>
<tr>
<td>Lower explosion limit</td>
<td>For solids not relevant</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>For solids not relevant</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>negligible</td>
</tr>
<tr>
<td>Bulk density</td>
<td>400 - 490 kg/m3</td>
</tr>
<tr>
<td>Vapour density</td>
<td>not relevant</td>
</tr>
<tr>
<td>Partitioning coefficient n-octanol/water (log Pow)</td>
<td>not applicable</td>
</tr>
</tbody>
</table>
10. Stability and Reactivity

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

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

Oxidizing properties:
not fire-propagating

Minimum ignition energy:
10 - 30 mJ, Inductivity: 1 mH (VDI 2263, sheet 1, 2.5)
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 charge. Avoid all sources of ignition: heat, sparks, open flame.

Incompatible materials
strong alkalies

Hazardous decomposition products

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

Thermal decomposition:
30 - 350 °C (DSC (DIN 51007))
No exothermic decomposition within the mentioned temperature range.

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. Ingestion may cause gastrointestinal disturbances. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

**Oral**
Type of value: LD50
Species: rat
Value: > 2,000 mg/kg (BASF-Test)

**Inhalation**
Type of value: LC50
Species: rat
Value: > 5.2 mg/l (OECD Guideline 403)
Exposure time: 4 h

**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
No data available.

Aspiration Hazard
No data available.

**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.

**Teratogenicity**
Assessment of teratogenicity: No indications of a developmental toxic / teratogenic effect were seen in animal studies.
Symptoms of Exposure
No significant symptoms are expected due to the non-classification of the product.

12. Ecological Information

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.

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.

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:
Dispose of in a licensed facility. Recommend crushing, puncturing or other means to prevent unauthorized use of used containers.
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:
Chemical TSCA, US released / listed
Pharma TSCA, US released / exempt

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

CERCLA RQ | CAS Number | Chemical name
--- | --- | ---
5000 LBS | 64-18-6 | Formic Acid
1000 LBS | 75-07-0 | acetaldehyde
10 LBS | 7439-92-1 | lead
1 LBS | 302-01-2 | hydrazine

State regulations

State RTK | CAS Number | Chemical name
--- | --- | ---
PA | 616-45-5 | 2-Pyrrolidone

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

WARNING: This product can expose you to chemicals including LEAD, which is known to the State of California to cause cancer and birth defects or other reproductive harm. 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
SDS Prepared on: 2018/10/10

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