

SAFETY DATA SHEET

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Safety Data Sheet

According to regulation (EC) No. 1907/2006 (REACH)

Klucel® GF Pharm

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Revised edition: 11.08.2017

Version: 1.3

Printed: 25.08.2022

1. Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product Identifier

Product Name: Klucel® GF Pharm

Article No.: 2440120, 2440121

UFI: --

1.2. Relevant identified Uses of the Substance or Mixture and Uses advised against

Identified uses:

*Rheological modifier
Pharmaceuticals*

Uses advised against:

1.3. Details of the Supplier of the Safety Data Sheet (Producer/Importer)

Company: Deffner & Johann GmbH

Address: Mühläckerstr. 13, D-Röthlein 97520, Germany

Tel./Fax.: Tel +49-9723-9350-0

Internet: www.deffner-johann.de

EMail: info@deffner-johann.de

Importer: --

1.4. Emergency No.

Emergency No.: +49-9723-9350-0

1.4.2 Poison Center:

2. Hazards Identification

2.1. Classification of the Substance or Mixture

*Classification according to Regulation
(EC) No. 1272/2008 (CLP/GHS)*

*This product does not require classification and labelling as
hazardous according to CLP/GHS.*

Possible Environmental Effects:

2.2. Label Elements

*Classification according to Regulation
(EC) No. 1272/2008 (CLP/GHS)*

No classification required according to the CLP/GHS guidelines.

Hazard designation:

Not applicable.

Signal word:

Hazard designation:

Safety designation:

Hazardous components for labelling:

2.3. Other Hazards

3. Composition/Information on Ingredients

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3. 1. Substance

3. 2. Mixture

Chemical Characterization: Hydroxypropyl cellulose, CAS No. 9004-64-2, EINECS 618-388-0

Information on Components / Hazardous Ingredients:

Additional information:

4. First Aid Measures

4. 1. Description of the First Aid Measures

General information:

No special measures required.

After inhalation:

Supply fresh air. Consult physician if symptoms persist.

After skin contact:

Wash off immediately with soap and plenty of water and rinse thoroughly.

If symptoms persist, consult a physician.

After eye contact:

Rinse open eye for several minutes under running water. Should irritation continue, seek medical advice.

After ingestion:

Do not give milk or alcoholic beverages to drink.

Never give anything by mouth to an unconscious person.

If symptoms persist consult physician.

4. 2. Most important Symptoms and Effects, both Acute and Delayed

Symptoms:

No further information available.

Effects:

4. 3. Indication of any Immediate Medical Attention and special Treatment needed

Treatment:

No special first-aid measures necessary.

5. Fire-Fighting Measures

5. 1. Extinguishing Media

Suitable extinguishing media:

Use extinguishing media for surrounding fire.

Foam, water jet.

Unsuitable extinguishing media:

5. 2. Special Hazards arising from the Substance or Mixture

Special hazards:

Dust can form explosive mixtures with air.

In case of fire: formation of carbon monoxide and dioxide.

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5.3. Advice for Firefighters

Protective equipment:

Wear self-contained respiratory protective device.

Further information:

Avoid contamination of sewage system, open water ways and ground water.

6. Accidental Release Measures

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Personal precautions:

Wear protective clothing.

Together with water product causes slippery surfaces.

Avoid inhalation of dust.

Keep unprotected persons out of danger zone.

6.2. Environmental Precautions

Environmental precautions:

Prevent contamination of soil, drains and surface waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods and material:

Take up mechanically and collect in suitable containers for disposal.

Avoid dust formation.

6.4. Reference to other Sections

Protective clothing, see Section 8.

See Section 13 for information on disposal.

7. Handling and Storage

7.1. Precautions for Safe Handling

Instructions on safe handling:

Provide adequate ventilation.

Avoid formation and deposition of dust. Provide adequate ventilation.

Hygienic measures:

Do not eat or drink during work. Do not smoke.

Do not inhale dust. Wash hands before breaks and at the end of work.

7.2. Conditions for Safe Storage, including any Incompatibilities

Storage conditions:

Store in tightly sealed containers in a dry and cool room.

Requirements for storage areas and containers:

Electrical installation/working materials must comply with the technological safety standards.

Information on fire and explosion protection:

Dust may form an explosive mixture with air.

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*Keep away from sources of heat and ignition - do not smoke.
Take measures to prevent static electricity discharge, earth/ground all equipment.
Dust explosion class 1 (Kst-value > 0 - 200 bar m/s).*

Storage class:

11; Combustible solids (TRGS 510)

Further Information:

7.3. Specific End Use(s)

Further information:

No information available.

8. Exposure Controls/Personal Protection

8.1. Parameters to be Controlled

Parameters to be controlled (DE):

Does not contain any components with workplace limit values.

Parameters to be controlled:

Derived No-Effect Level (DNEL):

Predicted No-Effect Concentration (PNEC):

Additional Information:

8.2. Exposure Controls

Technical protective measures:

Provide adequate ventilation in case of dust formation.

Personal Protection

General protective measures:

Keep away from foodstuffs and drinks. Do not eat, drink or smoke during work. Wash hands before breaks and at the end of work.

Respiratory protection:

None required under normal operating conditions.

Hand protection:

Protective gloves

Protective glove material:

Protective gloves made of butyl rubber.

Eye protection:

Tightly fitting safety goggles (EN 166).

Body protection:

Protective clothing.

Environmental precautions:

9. Physical and Chemical Properties

9.1. Information on Basic Physical and Chemical Properties

Form:

granules

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<i>Color:</i>	<i>whitish</i>
<i>Odor:</i>	<i>odorless</i>
<i>Odor threshold:</i>	<i>no information available</i>
<i>pH-Value:</i>	<i>5 - 8.5 (2 %)</i>
<i>Melting temperature:</i>	<i>100 - 150°C</i>
<i>Boiling temperature:</i>	<i>not determined</i>
<i>Flash point:</i>	<i>not applicable</i>
<i>Evaporation rate:</i>	<i>No information available.</i>
<i>Flammability (solid, gas):</i>	<i>Combustible dust</i>
<i>Upper explosion limit:</i>	<i>no information available</i>
<i>Lower explosion limit:</i>	<i>30 g/m³</i>
<i>Vapor pressure:</i>	<i>not applicable</i>
<i>Vapor density:</i>	
<i>Density:</i>	<i>> 1 g/cm³</i>
<i>Solubility in water:</i>	<i>insoluble > 45°C</i>
<i>Coefficient of variation (n-Octanol/Water):</i>	<i>no information available</i>
<i>Auto-ignition temperature:</i>	
<i>Decomposition temperature:</i>	<i>No data available.</i>
<i>Viscosity, dynamic:</i>	<i>not available</i>
<i>Explosive properties:</i>	<i>Dust can form explosive mixtures with air.</i>
<i>Oxidizing properties:</i>	<i>no information available</i>
<i>Bulk density:</i>	<i>500 kg/m³</i>

9.2. Further Information

Solubility in solvents:

Viscosity, kinematic:

Burning class:

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Solvent content:

Solid content:

Particle size:

Other information:

Dust deflagration index (Kst): < 200 m.b_/s

Dust explosion class: ST1

Minimal ignition energy: > 3 mJ

10. Stability and Reactivity

10.1. Reactivity

No decomposition if used according to specifications.

10.2. Chemical Stability

Stable if used according to specifications.

10.3. Possibility of Hazardous Reactions

Dust can form explosive mixtures with air.

Hazardous polymerisation will not occur.

10.4. Conditions to Avoid

Conditions to avoid:

Avoid heat, sparks, open fire and other ignition sources.

Thermal decomposition:

10.5. Incompatible Materials

None known.

10.6. Hazardous Decomposition Products

None known.

10.7. Further Information

11. Toxicological Information

11.1. Information on Toxicological Effects

Acute Toxicity

LD50, oral:

No information available.

LD50, dermal:

LC50, inhalation:

Primary effects

Irritant effect on skin:

Dust may cause irritation.

Irritant effect on eyes:

Product dust may cause irritation.

Inhalation:

Dust can cause irritation of the respiratory system.

Ingestion:

No information available

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Sensitization:

No sensitizing effects known.

Mutagenicity:

No mutagenic effects known.

Reproductive toxicity:

No negative effects known.

Carcinogenicity:

No negative effects.

Teratogenicity:

No information available.

Specific target organ toxicity (STOT):

No negative effects.

Additional toxicological information:

12. Ecological Information

12.1. Aquatic Toxicity

No information available.

Fish toxicity:

Daphnia toxicity:

Bacteria toxicity:

Algae toxicity:

12.2. Persistency and Degradability

Not readily biodegradable.

12.3. Bioaccumulation

No information available.

12.4. Mobility

No information available.

12.5. Results of PBT- und vPvP Assessment

Not applicable.

12.6. Other Adverse Effects

Water hazard class:

1, slightly hazardous

Behaviour in sewage systems:

Further ecological effects:

AOX Value:

13. Disposal Considerations

13.1. Waste Treatment Methods

Product:

Dispose of according to official national and local regulations.

European Waste Code (EWC):

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Uncleaned packaging:

Waste Code No.:

14. Transport Information

14.1. UN Number

ADR, IMDG, IATA

14.2. UN Proper Shipping Name

ADR/RID:

No hazardous goods according to ADR / DOT (US) (land transportation).

IMDG/IATA:

Not hazardous goods

14.3. Transport Hazard Classes

ADR Class:

not applicable

Hazard no.:

Classification code:

Tunnel restriction code:

IMDG Class (sea):

not applicable

Hazard no.:

EmS No.:

IATA Class:

not applicable

Hazard no.:

14.4. Packaging Group

ADR/RID:

not applicable

IMDG:

IATA:

14.5. Environmental Hazards

None

14.6. Special Precautions for User

Not classified as a dangerous good under transport regulations.

14.7. Transportation in Bulk according to Annex II of MARPOL 73/78 and IBC-Code

not applicable

14.8. Further Information

15. Regulatory Information

15.1. Safety, Health and Environmental Regulations/Legislation specific for the Substance or Mixture

Water hazard class:

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1, slightly hazardous for water (German Regulation)

Local regulations on chemical accidents:

Seveso III Directive: not applicable under Directive 2012/18/EC.

Employment restrictions:

Restriction and prohibition of application:

EC. REACH, Section XVII, Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles: not applicable

Technical instructions on air quality:

15.2. Chemical Safety Assessment

Exempted from the mandatory REACH Registration since this product is a polymer.

15.3. Further Information

Listed in the following inventories:

EINECS (EU), TSCA (US), AICS (AUS), DSL (CA), PICCS (PH), ENCS/ISHL (JP), KECI (KR), IECSC (CN), NZIoC (NZ), TSCI (TW)

EC. REACH, Annex XIV, Candidate List of Substances of very High Concern (SVHC): not regulated / not applicable

Regulation (EC) 850/2004 - Persistent organic pollutants and amending Directive 79/117/EEC: not regulated / not applicable

Regulation (EC) 1005/2009 - Substances that Deplete the Ozone Layer: not regulated / not applicable

16. Other Information

This product should be stored, handled and used in accordance with good hygiene practices and in conformity with any legal regulations. This information contained herein is based on the present state of knowledge and is intended to describe our product from the point of view of safety requirements. It should be therefore not be construed as guaranteeing specific properties.