

Safety Data Sheet

Product Name: DISOLCEL[®] Croscarmellose Sodium

The SDS is based on COMMISSION REGULATION (EU) 2020/878

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name	DISOLCEL [®] Croscarmellose Sodium
Type	Standard, GF
CAS No.	74811-65-7
Form	Powder (not nanoform)
Synonyms	Cross-linked sodium CMC
Unique formula identifier (UFI)	Not applicable
REACH No.	Does not require registration according to REACH

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Pharmaceutical excipient
Uses advised against	Not applicable

1.3. Details of the supplier of the safety data sheet

Manufacturer

MINGTAI CHEMICAL CO., LTD
1142, Shin Hsing Rd., Bah-Der District
Taoyuan City, Taiwan, R.O.C.
Phone: +886-3-3682295 / Fax: +886-3-3681438

Information Contact

E-mail: Sales@mingtai.com
Phone: +886-3-3682295

1.4. Emergency telephone number

Phone: +886-3-3682295

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008	Not hazardous
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2.2. Label elements

Classification according to Regulation (EC) No 1272/2008	Not hazardous
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2.3. Other hazards

Endocrine disrupting properties

According to Regulation (EU) 2017/2100, (EU) 2018/605 Not applicable

The substance is dry powder which is combustible.

SECTION 3: Composition/information on ingredients

3.1. Substances

Croscarmellose Sodium

Synonyms Cross-linked sodium CMC

CAS No. 74811-65-7

M-factor Not applicable

Acute Toxicity Not applicable

Form Powder (not nanoform)

3.2. Mixtures

Composition/information on ingredients

Chemical name	CAS no.	EINECS No.	Concentration (%)	Classification: EC 1272/2008 (CLP)	REACH registration number
Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant

(Full text of H- and EUH-phrases see SECTION 16)

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	Rinses thoroughly and immediately with plenty of water. If irritation occurs and persists, get medical attention
Ingestion	Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, get medical attention.
Inhalation	Remove to fresh air. Get medical attention for any breathing difficulty.
Skin contact	Wash off with water.
Personal protective equipment for first aid responders	No further information available

4.2. Most important symptoms and effects, both acute and delayed

Symptoms and effects No further information available

4.3. Indication of any immediate medical attention and special treatment needed

Treatment is symptomatic and supportive.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Water, dry chemical, foam or carbon dioxide.
Unsuitable extinguishing media	High pressure water jet

5.2. Special hazards arising from the substance or mixture

In case of fire	Carbon monoxide, carbon dioxide
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5.3. Advice for firefighters

In case of fire	Wearing full protective clothing and self-contained breathing apparatus
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Avoid dust formation and avoid breathing dust.
For emergency responder	Wearing self-contained breathing apparatus if exposed to dusts.

6.2. Environmental precautions

Reduce airborne dust and prevent scattering by moistening with water.

6.3. Methods and material for containment and cleaning up

Minimize dust generation.

Avoid to use airbrush for cleaning.

Sweep up the spilled material in a manner that does not disperse dust into the air.

6.4. Reference to other sections

Refer to protective measures in section 7 and 8.

Refer to disposal in section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Safe handling	Avoid dust generation and ensure good exhaust ventilation. Keep away from heat, spark, flame and other ignition source.
Hygiene measures	No smoking in work area. Remove soiled and contaminated clothing when leave the work area.

7.2. Conditions for safe storage, including any incompatibilities

Preserve in well-closed containers. No storage requirements specified.

7.3. Specific end use(s)

Not applicable

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit value

The product does not contain any substances with occupational exposure limit values established by the region specific regulatory bodies.

8.2. Exposure controls

Appropriate engineering controls	Use with local exhaust or ventilation facility.
Eye/face protection	Safety glasses, safety goggle, face-shield
Skin protection	Not required
Hand protection	Not required
Respiratory protection	Dust mask with filter type P1
Thermal hazards	Not applicable
Environmental exposure controls	No specific measures

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Physical state: powder	Color: white or greyish-white
Odor	Odorless	
Odor threshold	Not applicable	
pH	5.0-7. 0 (1.0% solid dispersion)	
Melting point/freezing point	Not applicable	
Initial boiling point and boiling range	Not applicable	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Lower and upper explosion limit	Not applicable	
Vapor pressure	Not applicable	
Relative vapor density	Not applicable	
Density and/or relative density	Not applicable	
Solubility	Swell in water and produce a viscous solution	
Partition coefficient: n-octanol/water	Not applicable	
Auto-ignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Kinematic viscosity	Not applicable	
Particle characteristics (D ₅₀ , by laser analyzer)	20-80 µm (volume-based)	

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Dust explosion class	St-1
K _{ST} value	153 bar-m/s
Maximum explosion pressure (P _{MAX})	8.3 bar-g
Maximum rate of pressure rise (R _{MAX})	563 bar/s
Explosible concentration of combustible dusts (MEC)	120 g/m ³
Limiting oxygen concentration for dust cloud combustion (LOC)	9.75 vol. %
Minimum ignition temperature of dust clouds (T _C)	330 °C
Auto-ignition temperature of a dust layer (T _L)	280 °C
Hot-surface ignition temperature of dust layers (T _S)	270 °C
Minimum ignition energy of a dust cloud in air (MIE)	120 mJ
Explosives	Not applicable
Flammable gases	Not applicable
Aerosols	Not applicable
Oxidising gases	Not applicable
Gases under pressure	Not applicable
Flammable liquids	Not applicable
Flammable solids	Not applicable
Self-reactive substances and mixtures	Not applicable
Pyrophoric liquids	Not applicable
Pyrophoric solids	Not applicable
Self-heating substances and mixtures	Not applicable
Substances and mixtures, which emit flammable gases in contact with water	Not applicable
Oxidising liquids	Not applicable
Oxidising solids	Not applicable
Organic peroxides	Not applicable
Corrosive to metals	Not applicable
Desensitised explosives	Not applicable

9.2.2 Other safety characteristics

Mechanical sensitivity	No information available
Self-accelerating polymerisation temperature	No information available
Formation of explosible dust/air mixtures	No information available
Acid/alkaline reserve	No information available
Evaporation rate	No information available
Miscibility	No information available
Conductivity	No information available
Corrosiveness	No information available

Gas group	No information available
Redox potential	No information available
Radical formation potential	No information available
Photocatalytic properties	No information available

SECTION 10: Stability and reactivity

10.1. Reactivity	Not applicable
10.2. Chemical stability	Stable under ordinary condition of use and storage
10.3. Possibility of hazardous reactions	Not applicable
10.4. Conditions to avoid	Heat, flame, ignition source and dusting
10.5. Incompatible materials	Not applicable
10.6. Hazardous decomposition products	No information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	Not applicable
Skin corrosion/irritation	Non-irritating
Serious eye damage/irritation	Non-irritating
Respiratory or skin sensitisation	Non-sensitizing
Germ cell mutagenicity	Not applicable
Carcinogenicity	Not applicable
Reproductive toxicity	Not applicable
STOT-single exposure	Not applicable
STOT-repeated exposure	Not applicable
Aspiration hazard	Not applicable

11.2. Information on other hazards

11.2.1 Endocrine disrupting properties	Not applicable
11.2.2 Other information	No information available

SECTION 12: Ecological information

12.1. Toxicity	No information available
12.2. Persistence and degradability	No information available
12.3. Bioaccumulative potential	No information available
12.4. Mobility in soil	No information available
12.5. Results of PBT and vPvB assessment	No information available
12.6. Endocrine disrupting properties	No information available
12.7. Other adverse effects	No information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product disposal	Disposal should be complied with all applicable local, state, and federal laws, rules, regulations, and standards.
Contaminated Packaging	Disposal should be complied with all applicable local, state, and federal laws, rules, regulations, and standards.

SECTION 14: Transport information

The product is not classified as hazardous material.

14.1. UN number or ID number	Not applicable
14.2. UN proper shipping name	Not applicable
14.3. Transport hazard class(es) (ADR/RID/IMDG/ICAO-TI/IATA-DGR)	Not applicable
14.4. Packing group	Not applicable
14.5. Environmental hazards	Not applicable
14.6. Special precautions for user	Not applicable
14.7. Maritime transportation in bulk according to IMO instruments	Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants	Not applicable
Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals	Not applicable
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III)	Not applicable

15.2. Chemical safety assessment

For this substance, a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of H- and EUH-phrases	Not applicable
Training advice	Not applicable
Abbreviations and acronyms	Not applicable

Key literature references and sources for data

Regulation (EC) No 1272/2008

Determination of combustion characteristics of a process dust (Report no. CRC-4770-2)

Revision date: 2021/05/01

The information in this Safety Data Sheet is based on our current knowledge and national laws. This document is intended only as a general and basic information for properly trained persons' understanding of the named product and is not intended to be given as product specifications, description, label, warning, notice, or any other document required by law.

End of Safety Data Sheet