

LOTTE FINE CHEMICAL AnyCoat-C (Hypromellose)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 11/15/2021 Version: 8.0 (Document No : E00CCPE-045)

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

1.1. Product identifier

Product form : Substance AnyCoat-C Product name

Name Hypromellose (Hydroxypropyl Methylcellulose)

9004-65-3 CAS-No. Chemical Family Cellulose ether

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Pharmaceutical excipient: Coating agent, Binder

1.2.2. Uses advised against

Restrictions on use : Not to be used for any purpose other than the one the product was designed for

1.3. Details of the supplier of the safety data sheet

Manufacturer

LOTTE Fine Chemical Co., Ltd. (Incheon Plant)

47, Namdongdaero 79beon-gil, Namdong-Gu, Incheon, 21700, Korea

T +82-32-899-0810 kw01.chang@lotte.net Supplier

TsafeE GmbH

Landwehrpl 6, 66111, Saarbruecken, Germany

T +49 177 9166175 shkim@tsafeg.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Germany	Giftinformationszentrum-Nord der Länder Bremen, Hamburg, Niedersachsen und Schleswig- Holstein (GIZ-Nord) Universitätsmedizin Göttingen - Georg-August-Universität	Robert-Koch Straße 40 37075 Göttingen	+49 (0) 551 19240	(English only)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Other hazards which do not result in classification

: Risk of dust explosion (Minimum explosive dust concentration: 55 g/m³, (1)). Could be ignited by heat, sparks or flame. May cause eye irritation. May cause irritation to skin. May cause irritation to the respiratory tract. Dust may cause painful eye irritation and tearing. Inhalation may cause irritation (cough, short breathing, difficulty in breathing).

The product does not meet the PBT and vPvB classification criteria

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SECTION 3: Composition/information on ingredients

3.1. Substances

Name : Hypromellose (Hydroxypropyl Methylcellulose)

CAS-No. : 9004-65-3

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hypromellose	(CAS-No.) 9004-65-3	100	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation

First-aid measures after skin contact

First-aid measures after eye contact

First-aid measures after ingestion

- : Remove person to fresh air and keep comfortable for breathing. If breathing stops, give artificial respiration. If breathing is difficult, give oxygen. Get medical advice/attention.
- : Wash skin thoroughly with mild soap and water. Continue to rinse for at least 15 minutes. Take off contaminated clothing and wash before reuse. Get medical advice/attention.
- Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove any contact lenses and open eyelids wide apart. Get medical advice/attention.

: Never give anything by mouth to an unconscious person. Do not induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Rinse mouth thoroughly with water. Give water to drink. Do not give mouth-to-mouth resuscitation if victim ingested or inhaled the substance. Get medical advice/attention.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water. Water spray. Dry chemical. Dry powder. Foam.

Unsuitable extinguishing media : Do not use a water jet since it may cause the fire to spread.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Risk of dust explosion. in presence of an ignition source. Avoid contact with oxidizing

agents (eg. chlorine, chromic acid etc.).

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO2). Toxic and irritating gases are released.

5.3. Advice for firefighters

Protection during firefighting

: Do not attempt to take action without suitable protective equipment. Use self-contained breathing apparatus and chemically protective clothing. Use extinguishing media appropriate for surrounding fire. Move containers from fire area if it can be done without personal risk. Do not scatter spilled material with high-pressure water streams. Avoid inhalation of the product. Do not breathe thermal decomposition products. Keep upwind.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures

: Avoid handling which leads to dust formation. Ventilate spillage area. Avoid inhalation of dust and contact with skin and eyes. Keep away from sources of ignition - No smoking. If spilled, may cause the floor to be slippery.

6.1.2. For emergency responders

Protective equipment

: Do not attempt to take action without suitable protective equipment. Wear protective clothing. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Avoid the spillage or runoff entering drains, sewers or watercourses.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

: Unauthorized persons are not admitted. Wear proper protective equipment. Clear up spills immediately and dispose of waste safely. Take precautionary measures against static discharge. Small spillages: Flush contaminated areas with plenty of water. In case of large spillages: Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Flush contaminated areas with plenty of water.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from strong acids, strong bases and oxidizing agents. Read and follow safety precautions on the solvent label and SDS. Avoid shock and friction. Ensure equipment is adequately earthed. Avoid handling which leads to dust formation. Provide local exhaust or general room ventilation. Use explosion-proof equipment. Avoid contact with skin, eyes and clothing. May be harmful if swallowed. May be harmful if inhaled. Wear proper protective equipment.

Hygiene measures

Do not eat, drink or smoke when using this product. Wash hands, contaminated skin thoroughly after handling. Take off immediately all contaminated clothing and wash it before reuse. Emergency eye wash fountain with clean water. Safety shower.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions

: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use explosion-proof equipment. Store in accordance with local regulations on explosives. Store at room temperature. Keep out of direct sunlight. Protect from moisture. Keep container closed when not in use. Store in a dry place. Store in a closed container. Store, if possible, in a cool, well ventilated place away from incompatible materials.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

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8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Local exhaust and general ventilation must be adequate to meet exposure standards. Do not exceed the occupational exposure limits (OEL). Use explosion-proof equipment. Ensure equipment is adequately earthed. Handle product only in closed system or provide appropriate exhaust ventilation.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):









8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. Chemical goggles

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. Antistatic clothing

Hand protection:

Chemically resistant protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

Wear suitable respiratory protection. Dust Respirator

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour : off-white to white.

Molecular mass : 10000 – 1500000 g/mol

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Appearance : Powder. Odour : odourless. Odour threshold Not available Melting point Not applicable Freezing point Not applicable Boiling point Not available Flammability Not applicable **Explosive limits** Not applicable

Lower explosive limit (LEL) : Minimum explosive dust concentration: 55 g/m3 (1)

Minimum explosive dust concentration as Methylcellulose: 85 g/m3

Upper explosive limit (UEL) : Not applicable Flash point : Not applicable

Auto-ignition temperature : 400 °C (Cefic Safety Instruction)

Decomposition temperature : Not applicable

pH : 5-8 (2% aqueous solution)

pH solution : Not available Viscosity, kinematic : Not applicable

Solubility : Soluble in: cold water. Ethanol-dichloromethane mixtures. Methanol-dichloromethane

mixtures. Water-alcohol mixtures.

Insoluble in: Chloroform. Ethanol (95%). Ether.

Partition coefficient n-octanol/water (Log Kow) : Not available : Not available Vapour pressure Vapour pressure at 50 °C : Not available Density $: > 0.2 \text{ g/cm}^3$ Relative density : Not available Relative vapour density at 20 °C : Not applicable : Not available Particle size : Not available Particle size distribution : Not available Particle shape Particle aspect ratio : Not available : Not available Particle aggregation state Particle agglomeration state : Not available Particle specific surface area : Not available Particle dustiness Not available

9.2. Other information

Specific gravity : 1.26

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts with: Strong acids. Strong bases. Strong oxidizing agents. Peroxides.

10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

10.3. Possibility of hazardous reactions

Could burn but does not ignite readily. Risk of dust explosion. On exposure to high temperature, may decompose, releasing toxic gases.

10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid handling which leads to dust formation.

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10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents. Peroxides. Combustible materials.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO2). Toxic and irritating gases are released.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

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LD50 oral rat Not classified (> 5200 mg/kg (2))

Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified (No sensitizing effect ; dust, rabbit (3))

Germ cell mutagenicity : Not classified (Negative; Ames test (3))
Carcinogenicity : Not classified (No carcinogenic effect; rat (4))

Reproductive toxicity : Not classified (No adverse effects expected; rat, rabbit (5))

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified (No adverse effects expected; rat (6))

Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse

effects in the environment.

Hazardous to the aquatic environment, short-term

(acute)

: Not classified

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

AnyCoat-C (Hypromellose) (9004-65-3)

The product does not meet the PBT and vPvB classification criteria

12.6. Endocrine disrupting properties

No additional information available

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12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

: Empty remaining contents. Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID n	14.1. UN number or ID number			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport 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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

AnyCoat-C (Hypromellose) is not on the REACH Candidate List

AnyCoat-C (Hypromellose) is not on the REACH Annex XIV List

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AnyCoat-C (Hypromellose) is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals.

AnyCoat-C (Hypromellose) is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the Canadian DSL (Domestic Substances List)

Germany

Employment restrictions

Water hazard class (WGK)
Hazardous Incident Ordinance (12. BImSchV)
Storage class (LGK, TRGS 510)
Joint storage table

Joint storage not permitted for Joint storage with restrictions permitted for Joint storage permitted for : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

: WGK 1, Slightly hazardous to water (Classification according to AwSV; ID No. 5294)

: Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

: LGK 13 - Non-combustible solids

LGK 1	LGK 2A	LGK 2B	LGK 3	LGK 4.1A
LGK 4.1B	LGK 4.2	LGK 4.3	LGK 5.1A	LGK 5.1B
LGK 5.1C	LGK 5.2	LGK 6.1A	LGK 6.1B	LGK 6.1C
LGK 6.1D	LGK 6.2	LGK 7	LGK 8A	LGK 8B
LGK 10	LGK 11	LGK 12	LGK 13	LGK 10-13

: LGK 1, LGK 6.2, LGK 7 : LGK 4.1A, LGK 5.1C : LGK 2A, LGK 2B, LGK 3, LGK 4.1

: LGK 2A, LGK 2B, LGK 3, LGK 4.1B, LGK 4.2, LGK 4.3, LGK 5.1A, LGK 5.1B, LGK 5.2, LGK 6.1A, LGK 6.1B, LGK 6.1C, LGK 6.1D, LGK 8A, LGK 8B, LGK 10, LGK 11, LGK 12, LGK 13, LGK 10-13

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose

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Lowest Observed Adverse Effect Level
No-Observed Adverse Effect Concentration
No-Observed Adverse Effect Level
No-Observed Effect Concentration
Organisation for Economic Co-operation and Development
Occupational Exposure Limit
Persistent Bioaccumulative Toxic
Predicted No-Effect Concentration
Regulations concerning the International Carriage of Dangerous Goods by Rail
Safety Data Sheet
Sewage treatment plant
Theoretical oxygen demand (ThOD)
Median Tolerance Limit
Volatile Organic Compounds
Chemical Abstract Service number
Not Otherwise Specified
Very Persistent and Very Bioaccumulative
Endocrine disrupting properties

Data sources

- : This safety data sheet was compiled with data and information from the following sources:
 - (1) Journal of the Society of Powder Technology, Japan Vol.32, No.1, 4-9 (1995)
 - (2) Registry of Toxic Effects of Chemical Substance, 655, (1978)
 - (3) Journal of the American College of Toxicology, Vol. 5(3), (1986)
 - (4) Journal of Pharmacology and Experimental Therapeutics. Vol. 99, 112-117 (1950)
 - (5) Toxicologist, 36, 259-260 (1997)
 - (6) Food and Chemical Toxicology 45, 2341-2351 (2007)

The classification complies with : ATP 12

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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