

CELLULOSUM MICROCRISTALLINUM ET
CARMELLOSUM NATRICUM

Publication: 19/09/2024
Revision: XX/XX/XXXX
Version: 00

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER

Product name: EN: Microcrystalline cellulose and carmellose sodium
LAT: Cellulosum microcristallinum et carmellosum natricum
NL: Microkristallijne cellulose en natriumcarmellose
FR: Cellulose microcristalline et carmellose sodique
DE: Mikrokristalline Cellulose und Carmellose-Natrium
N° CAS: 9004-34-6 (Microcrystalline Cellulose)
9004-32-4 (Sodium Carboxymethylcellulose)
N° EC: Not available.

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE/MIXTURE AND USES ADVISED AGAINST

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium
Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 EMERGENCY TELEPHONE NUMBER

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE/MIXTURE

Classification according to (EC) n° 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 (CLP).

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.
Signal word(s): Not applicable.
Hazard statements: Not applicable.
Precautionary statements: Not applicable.
Additional applicable label elements: Not applicable.

2.3 OTHER HAZARDS

WARNING. May form combustible dust concentrations in air.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Not applicable.

3.2 MIXTURES

Colloid-forming, powdered mixture of *Microcrystalline cellulose* (0316) with 5 per cent to 22 per cent of *Carmellose sodium* (0472).

Chemical name: Microcrystalline cellulose

N° CAS: 9004-34-6

N° EC: 232-674-9

Classification according to Regulation (EC) No. 1272/2008 (CLP): Not classified.

Chemical name: Sodium carboxymethylcellulose

N° CAS: 9004-32-4

N° EC: Not available.

Classification according to Regulation (EC) No. 1272/2008 (CLP): Not classified.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General notes: When in doubt or if symptoms are observed, get medical advice.

After inhalation: IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

After skin contact: IF ON SKIN: Wash with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.

After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

After ingestion: IF SWALLOWED: Never give anything by mouth to an unconscious person. Drink plenty of water. Get medical attention if symptoms occur.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Get medical attention if irritation or other symptoms occur.

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: Foam. Dry powder. Water spray. Carbon dioxide (CO₂).

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Unsuitable extinguishing media:

Keep product and empty container away from heat and sources of ignition. Do not use water jetstream.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires:

Not available.

Protection against fire:

Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

FOR NON-EMERGENCY PERSONNEL

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Use personal protection recommended in section 8. Sweep up to prevent slipping hazard.

FOR EMERGENCY RESPONDERS

Use personal protection recommended in section 8.

6.2 ENVIRONMENTAL PRECAUTIONS

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Methods for containment: Sweep up and shovel into suitable containers for disposal. Avoid dust formation. Dispose of in accordance with local regulations.

Methods for cleaning up: Use industrial vacuum cleaners approved for combustible dust and area electrical classification.

6.4 REFERENCE TO OTHER SECTIONS

See section 8 for more information.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling:

Avoid generation of dust and aerosols. Avoid contact with eyes, skin and clothing. Minimise dust generation and accumulation. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Handling and processing operations should be conducted in accordance with 'best practices' (e.g. NFPA-654).

Personal protection:

Not available.

Technical protective measures:

Not available.

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Handling:

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with eyes, skin and clothing. Wear suitable gloves and eye/face protection.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage: Keep/store only in original container.
Conditions for safe storage, including any incompatibilities: Keep container tightly closed in a dry and well-ventilated place.
Storage – away from: Not available.

7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Exposure limits: Based on data available for ingredients.

Chemical name	European Union	United Kingdom		France	Spain
Microcrystalline cellulose 9004-34-6	-	20 mg/m ³ STEL (inhalable dust); 12 mg/m ³ STEL (calculated, respirable dust) 10 mg/m ³ inhalable dust 4 mg/m ³ respirable dust		TWA: 10 mg/m ³	TWA: 10 mg/m ³
	Italy	Portugal	Netherlands	Finland	Denmark
	-	TWA: 10 mg/m ³	-	-	TWA: 1 mg/m ³
	Austria	Switzerland	Poland	Norway	Ireland
	-	TWA: 3 mg/m ³	TWA: 3 mg/m ³	-	TWA: 10 mg/m ³ STEL: 30 mg/m ³
	Belgium	Sweden	Croatia	Turkey	Germany
	TWA: 10 mg/m ³	NGV: 2 mg/m ³	TWA: 10 mg/m ³ TWA: 4 mg/m ³ STEL: 20 mg/m ³	-	-

8.2 EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROL

Engineering controls: Ensure adequate ventilation. Avoid generation of dust and aerosols.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with eyes, skin and clothing. Wear suitable gloves and eye/face protection.

INDIVIDUAL PROTECTION MEASURES

Eye/face protection: No special protective equipment required.
Skin protection: Wear protective gloves and protective clothing.
Hand protection: Wear protective gloves.

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Respiratory protection: If exposure limits are likely to be exceeded or if irritation or other symptoms are experienced, NIOSH/MSHA or EN 136 approved respiratory protection should be worn.

Thermal hazards: Not determined.

ENVIRONMENTAL EXPOSURE CONTROL

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White or off-white, coarse or fine, hygroscopic powder.

Odour: Odourless.

Odour threshold: Not available.

pH: 6.0 - 8.0

Melting/freezing point: Not available.

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Practically insoluble in organic solvents and in dilute acids.

Solubility in water: Dispersible in water producing a white, opaque colloidal dispersion.

Partition coefficient (n-octanol/water): Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: 60 per cent to 140 per cent of the nominal value.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 OTHER INFORMATION

Sensitivity to mechanical impact: No.

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Not expected.

10.2 CHEMICAL STABILITY

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Stability

Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact: No.

Sensitivity to static discharge: Yes.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Possibility of hazardous reactions: None under normal processing.

Hazardous polymerization: Hazardous polymerisation does not occur.

10.4 CONDITIONS TO AVOID

Heat, flames and sparks. May form combustible dust concentrations in air.

10.5 INCOMPATIBLE MATERIALS

Keep away from heat, flames and sparks.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Chemical name:	Microcrystalline Cellulose 9004-34-6	Sodium carboxymethylcellulose 9004-32-4
Acute toxicity:	Dermal LD ₅₀ : > 2 g/kg (Rabbit) Dermal LD ₅₀ : > 2000 mg/kg (Rabbit) Inhalation LC ₅₀ : > 5800 mg/m ³ (Rat) 4h	Oral LD ₅₀ : 27000 mg/kg (Rat) Dermal LD ₅₀ : > 2 g/kg (Rabbit) Inhalation LC ₅₀ : > 5800 mg/m ³ (Rat) 4h
Skin corrosion/irritation:	May cause skin irritation.	Not expected.
Serious eye damage/irritation:	May cause irritation.	May cause slight irritation.
Respiratory/skin sensitisation:	Not available.	Not expected.
Germ cell mutagenicity:	Not available.	Not expected.
Carcinogenicity:	Not available.	Not expected.
Reproductive toxicity:	Not expected.	Not expected.
Summary of evaluation of the CMR properties:	Not available.	
STOT-single exposure:	Not available.	
STOT-repeated exposure:	Not available.	
Aspiration Hazard:	Not available.	
Other:	Symptoms: Get medical attention if irritation or other symptoms occur. Endocrine disrupting properties: This product does not contain any known or suspected endocrine disruptors.	

11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.

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Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium carboxymethylcellulose 9004-32-4	ErC ₅₀ : >500 mg/l (<i>Selenastrum capricornutum</i>)	LC ₅₀ : 1,414 mg/l (<i>Danio rerio</i>)	EC ₅₀ : 1,141 mg/l (<i>Daphnia magna</i>)	-

12.2 PERSISTENCE AND DEGRADABILITY

Chemical name	Biodegradation
Sodium carboxymethylcellulose 9004-32-4	Not readily biodegradable (0% after 28 days).

12.3 BIOACCUMULATIVE POTENTIAL

Not available.

12.4 MOBILITY IN SOIL

Not available.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

Not available.

12.6 OTHER ADVERSE EFFECTS

Endocrine disrupting properties: This product does not contain any known or suspected endocrine disruptors.

Water hazard class (WGK): Microcrystalline cellulose (9004-34-6): Non-hazardous to water
Sodium carboxymethylcellulose (9004-32-4): Class 1

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Waste from residues/unused products: Dispose of wastes in an approved waste disposal facility. Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable.

Contaminated packaging: Dispose of empty containers and wastes safely. Dispose of waste product or used containers according to local regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN NUMBER

ADR/ RID(Land),IMDG(Sea), Not regulated.
IATA/ICAO (Air) :

14.2 UN PROPER SHIPPING NAME

ADR/ RID(Land),IMDG(Sea), Not regulated.
IATA/ICAO (Air) :

14.3 TRANSPORT HAZARD CLASS(ES)

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ADR/ RID(Land),IMDG(Sea), Not regulated.
IATA/ICAO (Air) :

14.4 PACKING GROUP

ADR/ RID(Land),IMDG(Sea), Not regulated.
IATA/ICAO (Air) :

14.5 ENVIRONMENTAL HAZARDS

ADR/ RID(Land),IMDG(Sea), Not applicable.
IATA/ICAO (Air) :

14.6 SPECIAL PRECAUTIONS FOR USER

None.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not available.

14.8 ADDITIONAL TRANSPORT INFORMATION

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE/MIXTURE

Hazard symbol: Not applicable.
Risk phrases: Not applicable.
Safety phrases: Not applicable.

15.2 CHEMICAL SAFETY ASSESSMENT

Not available.

SECTION 16: OTHER INFORMATION

16.1 CHANGES SINCE THE PREVIOUS VERSION

Not applicable.

16.2 ABBREVIATIONS AND ACRONYMS USED

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

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16.3 KEY LITERATURE REFERENCES/SOURCES FOR DATA

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 METHOD OF CLASSIFICATION IN CASE OF MIXTURE

Classification based on the main component.

16.5 RELEVANT HAZARD STATEMENTS AND/OR PRECAUTIONARY STATEMENTS

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 TRAINING ADVISEMENT

Not available

16.7 NOTICE FOR USER(S)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 DEPARTMENT ISSUING MSDS

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