

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## CELLULOSUM MICROCRISTALLINUM

EN

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

#### 1.1 Product identifier

Product name: Cellulose, microcrystalline  
Cellulosum microcristallinum  
Microkristallijn cellulose  
Cellulose microcristalline  
Mikrokristalline Cellulose

N° CAS: 9004-34-6

N° EC: 232-674-9

#### 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: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
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

Not classified.

#### 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

Not available.

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Cellulose, microcrystalline
IUPAC name:	2-[4,5-dihydroxy-2-(hydroxymethyl)-6-methoxyoxan-3-yl]oxy-6-(hydroxymethyl)-5-methoxyoxane-3,4-diol
Synonyms:	Cellulosepulver Diethylaminoethyl cellulose
N° CAS:	9004-34-6
N° EC:	232-674-9
Molecular Formula:	$C_{6n}H_{10n+2}O_{5n+1}$
Content:	100%

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

After inhalation:	Supply fresh air; consult a doctor in case of complaints.
After skin contact:	Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
After eye contact:	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
After ingestion:	Wash mouth with water. Call for a doctor immediately.

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

Not available.

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

Not available.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Water, fire-extinguishing powder, foam, carbon dioxide.
Unsuitable extinguishing media:	Not available.

#### 5.2 Special hazards arising from the substance/mixture

In case of fire, the following can be released:  
Carbon monoxide (CO)  
CO<sub>2</sub>.

#### 5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Mount respiratory protective device. Wear self-contained respiratory protective device.
Hazardous combustion products:	Not available.

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### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Wear protective equipment. Keep unprotected persons away. Avoid formation of dust. Mount respiratory protective device.

##### For emergency responders

Wear protective equipment. Keep unprotected persons away. Avoid formation of dust. Mount respiratory protective device.

#### 6.2 Environmental precautions

Do not allow to penetrate the ground/soil.

Do not allow to enter sewers/surface or ground water.

#### 6.3 Methods and material for containment and cleaning up

Pick up mechanically.

#### 6.4 Reference to other sections

See section 7 for information on safe handling.

See section 8 for information on personal protection equipment.

See section 13 for disposal information.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling:

Keep ignition sources away. Do not smoke.

Personal protection:

Not available.

Technical protective measures:

Prevent formation of dust. Ensure good ventilation/exhaustion at the workplace. Any unavoidable deposit of dust must be regularly removed. Protect against electrostatic charges. Dust can combine with air to form an explosive mixture.

Handling:

Not available.

#### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store only in the original receptacle. Store in well-sealed receptacles. Storage class: VCI: 10 – 13.

Conditions for safe storage, including any incompatibilities:

Store in cool, dry conditions. Store in a well-ventilated area.

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

WEL:

Short-term value: 20 mg/m<sup>3</sup> (inhalable dust)

Long-term value: 10 mg/m<sup>3</sup> (inhalable dust)

4 mg/m<sup>3</sup> (respirable)

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### 8.2 Exposure controls

#### Appropriate engineering control

The usual precautionary measures are to be adhered to when handling chemicals.

#### Individual protection measures

Eye/face protection: Tightly sealed goggles. EN 166.

Skin protection: Protective work clothing.

Hand protection: Protective gloves.

Material of gloves: EN 374. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection: In case of brief exposure or low pollution, use respiratory filter device. In case of intensive or longer exposure, use self-contained respiratory protective device. Filter P2. Filter P3. EN 149.

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 almost white, fine or granular, slightly hygroscopic powder.

Odour: Odourless.

Odour threshold: Not available.

pH: 5.0 to 7.5

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): Product is not flammable.

Upper/lower flammability or explosive limits: Lower: 30 g/m<sup>3</sup>  
Upper: 11 000 g/m<sup>3</sup>

Vapour pressure: 0 hPa (20 °C)

Vapour density: 1.5 g/cm<sup>3</sup> (20 °C)

Relative density: Not available.

Solubility: Practically insoluble in acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/L solution of sodium hydroxide.

Solubility in water: Practically insoluble.

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

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Auto-ignition temperature:	500 °C
Decomposition temperature:	200 °C
Viscosity:	Not available.
Explosive properties:	Risk of dust explosion.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not determined.

### 10.2 Chemical stability

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Based on available data, the classification criteria are not met. Oral LD50 (rat): > 3 000 mg/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

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

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Not available.

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not applicable.

#### 12.6 Other adverse effects

Not available.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste.

Contaminated packaging: Recommendation: Disposal must be made according to official regulations.

### SECTION 14: TRANSPORT INFORMATION

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

##### 14.1 UN Number

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

##### 14.2 UN proper shipping name

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

##### 14.3 Transport hazard class(es)

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

##### 14.4 Packing group

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

##### 14.5 Environmental hazards

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

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### 14.6 Special precautions for user

Not available.

### 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

Not applicable.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

## 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

### 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

Not applicable.

### 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

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### 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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