

Material Safety Data Sheet

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

CARMELLOSUM NATRICUM

EN

FORM-06-14-01 (V00)

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

1.1 Product identifier

Product name:	Carmellose sodium Carmellosum natricum Natrium carmellose Carmellose sodique Carmellose-Natrium
N° CAS:	9004-32-4
N° EC:	618-378-6

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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 a hazardous substance or mixture.

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.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Carmellose sodium
IUPAC name:	Sodium;2,3,4,5,6-pentahydroxyhexanal;acetate
Synonyms:	Carboxymethylcellulose sodium (USP) Celluvisc (TN)
N° CAS:	9004-32-4
N° EC:	618-378-6
Molecular Formula:	$C_8H_{15}NaO_8$
Content:	6.5 per cent to 10.8 per cent of sodium (Na) (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	No hazards which require special first aid measures.
After inhalation:	If breathed in, move person into fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
After skin contact:	First aid is not normally required. However, it is recommended that exposed areas be cleaned by washing with soap and water.
After eye contact:	Remove contact lenses. Protect unharmed eye.
After ingestion:	Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: No hazards which require special first aid measures.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray. Foam.
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Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: Carbon dioxide (CO₂), carbon monoxide.

5.3 Advice for firefighters

Surrounding fires: Product is compatible with standard fire-fighting agents. Further information: Standard procedure for chemical fires.

Protection against fire: In the event of fire, wear self-contained breathing apparatus.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation. Avoid breathing dust. Persons not wearing protective equipment should be excluded from area of spill until clean-up has been completed. Comply with all applicable federal, state, and local regulations.

For emergency responders

Avoid dust formation. Avoid breathing dust. Persons not wearing protective equipment should be excluded from area of spill until clean-up has been completed. Comply with all applicable federal, state, and local regulations.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For further information, see section 8 (individual protection measures) and section 13 (disposal considerations).

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid dust formation. Smoking, eating and drinking should be prohibited in the application area.

Personal protection: For personal protection see section 8. Avoid breathing dust.

Technical protective measures: Take measures to prevent the build up of electrostatic charge. Provide appropriate exhaust ventilation at places where dust is formed.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: No decomposition if stored and applied as directed.

Conditions for safe storage, including any incompatibilities: Not available.

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Storage – away from:

UV light. Exposure to sunlight. Keep away from heat, flame, sparks and other ignition sources.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering control

Provide appropriate exhaust ventilation at places where dust is formed. General room ventilation should be adequate for normal conditions of use. However, if unusual operating conditions exist, provide sufficient mechanical (general and/or local exhaust) ventilation to maintain exposure below exposure guidelines (if applicable) or below levels that cause known, suspected or apparent adverse effects.

Individual protection measures

Eye/face protection: Safety glasses. Use eye protection according to EN 166.

Skin protection: Wear as appropriate: Safety shoes complying with EN ISO 20345, protective clothing complying with EN 13688.

Hand protection: Material: butyl-rubber. Break through time: 480 min. Glove thickness: > 0,5 mm.
Remarks: The exact break through time can be obtained from the protective glove producer and this has to be observed. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Respiratory protection: In the case of dust or aerosol formation, use respirator with an approved filter within the capabilities of the respirator/filter combination. Where concentrations are above recommended limits or are unknown, or a cartridge type respirator is not adequate, wear a positive-pressure supplied-air respirator. Respiratory protection complying with EN 136. Respiratory protection complying with EN 140. Respiratory protection complying with EN 14387.

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, granular powder, hygroscopic after drying.

Odour: Not available.

Odour threshold: Not available.

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pH:	6.5 – 8.5 (as aqueous solution)
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 acetone, in anhydrous ethanol and in toluene.
Solubility in water:	It is easily dispersed in water giving colloidal solutions.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	550 mPa.s (20 g/L solution)
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Product will not undergo hazardous polymerization.

10.4 Conditions to avoid

UV light. Exposure to sunlight.

Keep away from heat, flame, sparks and other ignition sources.

10.5 Incompatible materials

Acids, bases, oxidising agents.

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10.6 Hazardous decomposition products

Carbon monoxide.
Carbon dioxide (CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not classified based on available information.
Skin corrosion/irritation:	Not classified based on available information.
Serious eye damage/irritation:	Not classified based on available information.
Respiratory/skin sensitisation:	Not classified based on available information.
Germ cell mutagenicity:	Not classified based on available information.
Carcinogenicity:	Not classified based on available information.
Reproductive toxicity:	Not classified based on available information.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified based on available information.
STOT-repeated exposure:	Not classified based on available information.
Aspiration Hazard:	Not classified based on available information.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Unlikely to cause eye irritation or injury. Product dust may be irritating to eyes.
Skin contact:	Product dust may be irritating to skin.
Inhalation:	Product dust may be irritating to respiratory system.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Biodegradability:
Result: Inherently biodegradable.
Biodegradation: 52 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

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12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Assessment:

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Contaminated packaging: Empty remaining contents.

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.

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

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Not dangerous goods.

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

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

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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

Quality Department

FAC SECUNDUM ARTEM NV

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