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

1.1 Product identifier

Product name: Methylcellulose

Methylcellulosum Methylcellulose Méthylcellulose Methylcellulose

N° CAS: 9004-67-5 N° EC: 618-391-7

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

This product is not classified as dangerous according to EC criteria.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

elements:

2.3 Other hazards

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Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Methylcellulose

IUPAC name: (5R)-2,3,4-trimethoxy-6-(methoxymethyl)-5-[(2S)-3,4,5-trimethoxy-6-(methoxymethyl)

yl)oxan-2-yl]oxyoxane

Synonyms: Cellulose, methyl ether

 N° CAS: 9004-67-5 N° EC: 618-391-7 Molecular Formula: $C_{20}H_{38}O_{11}$

Content: 26.0 per cent to 33.0 per cent of methoxy groups (-OCH3; Mr 31.03) (dried

substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: If potential for exposure exists, refer to section 8 for specific personal protective

equipment.

After inhalation: Move person to fresh air; if effects occur, consult a physician.

After skin contact: Wash skin with plenty of water.

After eye contact: Flush eyes with plenty of water; remove contact lenses after the first 1-2 minutes,

then continue flushing for several minutes. Only mechanical effects expected. If

effects occur, consult a physician, preferably an ophthalmologist.

After ingestion: No emergency medical treatment necessary.

4.2 Most important symptoms and effects, both acute and delayed

Aside from the information found under Description of first aid measures (above) and Indication of immediate medical attention and special treatment needed (below), no additional symptoms and effects are anticipated.

4.3 Indication of any immediate medical attention and special treatment needed

No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water. Dry chemical fire extinguishers. Carbon dioxide fire

extinguishers.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

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Hazardous combustion products: During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating. Combustion products may include and are not limited to: Carbon monoxide. Carbon dioxide.

Unusual fire and explosion hazards: Do not permit dust to accumulate. When suspended in air, dust can pose an explosion hazard. Minimize ignition sources. If dust layers are exposed to elevated temperatures, spontaneous combustion may occur. Pneumatic conveying and other mechanical handling operations can generate combustible dust. To reduce the potential for dust explosions, electrically bond and ground equipment and do not permit dust to accumulate. Dust can be ignited by static discharge.

5.3 Advice for firefighters

Surrounding fires: Keep people away. Isolate fire and deny unnecessary entry. Soak

thoroughly with water to cool and prevent re-ignition. Cool surroundings with water to localize fire zone. Hand held dry chemical or carbon dioxide extinguishers may be used for small fires. Dust explosion hazard may result from forceful application of fire

extinguishing agents.

Protection against fire: Wear positive-pressure self-contained breathing apparatus (SCBA)

and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe

distance.

Hazardous combustion products: Carbon monoxide. Carbon dioxide.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Spilled material may cause a slipping hazard. Use appropriate safety equipment. For additional information, refer to section 8, Exposure Controls and Personal Protection.

For emergency responders

Spilled material may cause a slipping hazard. Use appropriate safety equipment. For additional information, refer to section 8, Exposure Controls and Personal Protection.

6.2 Environmental precautions

Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. See section 12, Ecological Information.

6.3 Methods and material for containment and cleaning up

Contain spilled material if possible. Sweep up. Use care to minimize generation of airborne dust. Do not use water for cleanup. Collect in suitable and properly labeled containers. See section 13, Disposal Considerations, for additional information.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

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Precautions for safe handling: Keep away from heat, sparks and flame. No smoking, open flames or

sources of ignition in handling and storage area.

Personal protection: See section 8, Exposure controls and Personal protection.

Technical protective measures: Electrically ground and bond all equipment. Good housekeeping and

controlling of dusts are necessary for safe handling of product. Pneumatic conveying and other mechanical handling operations can generate combustible dust. To reduce the potential for dust explosions, electrically bond and ground equipment and do not permit dust to accumulate. Dust can be ignited by static discharge.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Store in a dry place. See Section 10 for more specific information.

Storage temperature: 5 - 35 °C

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

TWA total dust: 10 mg/m³

8.2 Exposure controls

Appropriate engineering control

Ventilation: Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, general ventilation should be sufficient for most operations. Local exhaust ventilation may be necessary for some operations.

Individual protection measures

Eye/face protection: Use safety glasses (with side shields). Safety glasses (with side shields) should be

consistent with EN 166 or equivalent. If there is a potential for exposure to particles which could cause eye discomfort, wear chemical goggles. Chemical goggles should

be consistent with EN 166 or equivalent.

Skin protection: No precautions other than clean body-covering clothing should be needed.

Hand protection: Chemical protective gloves should not be needed when handling this material.

Consistent with general hygienic practice for any material, skin contact should be

minimised.

Respiratory protection: Respiratory protection should be worn when there is a potential to exceed the

exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, wear respiratory protection when adverse effects, such as respiratory irritation or discomfort have been experienced, or where indicated by your risk assessment process. For most conditions, no respiratory protection should

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be needed; however, in dusty atmospheres, use an approved particulate respirator. Use the following CE approved air-purifying respirator: Particulate filter, type P2.

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, yellowish-white or greyish-white powder or granules, hygroscopic after

drying.

Odour: Odorless.

Odour threshold: Not available.

pH: Not applicable.

Melting/freezing point: Not available.

Initial boiling point:

Boiling range:

Not applicable.

Flash point:

Not available.

Evaporation rate: Not applicable to solids.

Flammability (solid/gas): No.

Upper/lower flammability or

explosive limits:

Not available.

Vapour pressure: Not applicable.
Vapour density: Not applicable.
Relative density: Not available.

Solubility: Practically insoluble in acetone, in anhydrous ethanol and in toluene.

Solubility in water: Practically insoluble in hot water. It dissolves in cold water giving a colloidal solution.

Partition coefficient Not available.

(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Kinematic viscosity: Not applicable.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

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No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under recommended storage conditions. See storage, section 7.

10.3 Possibility of hazardous reactions

Polymerisation will not occur.

10.4 Conditions to avoid

Avoid temperatures above 130 °C. Exposure to elevated temperatures can cause product to decompose. Avoid static discharge.

10.5 Incompatible materials

Avoid contact with oxidising materials. Avoid contact with: Strong acids. Strong bases.

10.6 Hazardous decomposition products

Decomposition products depend upon temperature, air supply and the presence of other materials.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Ingestion: Very low toxicity if swallowed. Harmful effects not anticipated from

swallowing small amounts. LD₅₀ (rat): > 10 000 mg/kg

Aspiration hazard: Based on physical properties, not likely to be an aspiration hazard. Dermal: No adverse effects anticipated by skin absorption. The dermal LD_{50} has not

been determined.

Inhalation: No adverse effects are anticipated from single exposure to dust. For respiratory irritation and narcotic effects: No relevant data found. As product: The

LC₅₀ has not been determined.

Skin corrosion/irritation: Essentially non-irritating to skin.

Serious eye damage/irritation: Essentially non-irritating to eyes. Solid or dust may cause irritation or corneal injury

due to mechanical action.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: In animal studies, a similar cellulosic has been shown not to interfere with

reproduction.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.

Other: Repeated Dose Toxicity: Repeated ingestion of similar cellulosics by humans has not

resulted in known significant adverse effects.

Chronic Toxicity and Carcinogenicity: Similar cellulosics did not cause cancer in

long-term animal studies.

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Developmental Toxicity: Similar cellulosics did not cause birth defects or other toxic

effects to the fetus in laboratory animal studies.

Genetic Toxicology: Similar cellulosics were negative in both in vitro and animal

genetic toxicity studies.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Skin contact:

Not available.

Inhalation:

Not available.

Not available.

Not available.

Not available.

Not available.

Aspiration:

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not expected to be acutely toxic to aquatic organisms.

12.2 Persistence and degradability

No appreciable biodegradation is expected. Biological oxygen demand (BOD): BOD 20: 0%

12.3 Bioaccumulative potential

Bioaccumulation: No bioconcentration is expected because of the relatively high molecular weight (MW greater than 1000).

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance has not been assessed for persistence, bioaccumulation and toxicity (PBT).

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Any disposal practice must be in compliance with all local and national laws and regulations. Do not dump into any sewers, on the ground, or into any body of water.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

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ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

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

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

15.2 Chemical safety assessment

Not applicable.

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

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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 Bioaccumalative

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

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

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