

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



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

1.1 Product identifier

Product name: Hypromellose
Hypromellosum
Hypromellose
Hypromellose
Hypromellose

N° CAS: 9004-65-3

N° EC: 618-389-6

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 substance does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

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.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



HYPROMELLOSUM

2.3 Other hazards

Dust explosion hazards.

Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Hypromellose
IUPAC name:	2-[6-[4,5-bis(2-hydroxypropoxy)-2-(2-hydroxypropoxymethyl)-6-methoxyoxan-3-yl]oxy-4,5-dimethoxy-2-(methoxymethyl)oxan-3-yl]oxy-6-(hydroxymethyl)-5-methoxyoxane-3,4-diol
Synonyms:	Hydroxypropyl methylcellulose HPMC
N° CAS:	9004-65-3
N° EC:	618-389-6
Molecular Formula:	Not available
Content:	Methoxy (-OCH ₃ ; M _r 31.03) and hydroxypropoxy (-OC ₃ H ₆ OH ; M _r 75.09) groups (dried substance) conforming to the types of Hypromellose. Substitution type 2910: - Methoxy %: 28.0 to 30.0; - Hydroxypropoxy %: 7.0 to 12.0.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Take off contaminated clothing and wash it before reuse. In all cases of doubt, or when symptoms persist, seek medical advice.
After inhalation:	Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.
After skin contact:	Wash with plenty of soap and water. 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. In all cases of doubt, or when symptoms persist, seek medical advice.
After ingestion:	Rinse mouth immediately and drink plenty of water. Get medical advice/attention if you feel unwell.

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

None.

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water, foam, alcohol resistant foam, fire extinguishing powder.
Unsuitable extinguishing media:	Water jet.

5.2 Special hazards arising from the substance/mixture

Hazardous decomposition products: Section 10.
Danger of dust explosion.
Deposited combustible dust has considerable explosion potential.
Hazardous combustion products: carbon monoxide (CO), carbon dioxide (CO₂), formaldehyde.

5.3 Advice for firefighters

Surrounding fires:	In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.
Protection against fire:	Self-contained breathing apparatus (EN 133).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Keep away from sources of ignition - No smoking. Do not breathe dust. Special danger of slipping by leaking/spilling product. Wear suitable protective equipment (including personal protective equipment referred to under section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Knock down dust with water spray.
Keep away from drains, surface and ground water.
Retain contaminated washing water and dispose it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill: take up mechanically.
Advice on how to clean up a spill: Take up mechanically. Collect spillage. Product residues: to clean the floor and all objects contaminated by this material, use plenty of water.
Other information relating to spills and releases: Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



Hazardous combustion products: see section 5.

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Specific notes/details: Layers, deposits and heaps of combustible dust must be considered, like any other source which can form a hazardous explosive atmosphere. Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion. Danger of dust explosion.

Measures to protect the environment: Avoid release to the environment.

Personal protection:

Advice on general occupational hygiene: Do not to eat, drink and smoke in work areas. Wash hands after use. Preventive skin protection (barrier creams/ointments) is recommended. Remove contaminated clothing and protective equipment before entering eating areas.

Technical protective measures:

Measures to prevent fire as well as aerosol and dust generation: Use local and general ventilation. Take precautionary measures against static discharge. Only vacuum cleaners containing no ignition sources may be used for combustible dusts. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Keep only in original container.

Conditions for safe storage, including any incompatibilities:

Hygroscopic solid. Store in a dry place. Keep container tightly closed. Keep cool. Keep only in original container.

Ventilation requirements: Provision of sufficient ventilation.

Take precautionary measures against static discharge. Ground/bond container and receiving equipment.

Explosive atmospheres: Removal of dust deposits. Only vacuum cleaners containing no ignition sources may be used for combustible dusts.

Storage – away from:

Incompatible materials: see section 10.

Protect against heat and humidity. Protect from sunlight.

Keep away from food, drink and animal feed.

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

Occupational exposure limit values (Workplace Exposure Limits):

Country	Name of agent	Notation	Identifier	TWA
GB	Dust	Inhalable fraction (i)	WEL	10 mg/m ³
GB	Dust	Respirable fraction (r)	WEL	4 mg/m ³

8.2 Exposure controls

Appropriate engineering control

General ventilation.

Individual protection measures

Eye/face protection: Wear eye/face protection.

Skin protection: Not determined.

Hand protection: Wear suitable gloves.

Material: CR: chloroprene (chlorobutadiene) rubber

Material thickness: ≥ 0,65 mm

Breakthrough times of the glove material: > 480 minutes (permeation: level 6)

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Respiratory protection: Particulate filter device (EN 143). Avoid breathing dust.

Thermal hazards: Not determined.

Environmental exposure control

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

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.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



HYPROMELLOSUM

Odour:	Nearly odourless.
Odour threshold:	Not available.
pH:	5.0 to 8.0 (water: 20 g/l, 20 °C)
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not available.
Flammability (solid/gas):	Danger of dust explosion.
Upper/lower flammability or explosive limits:	Lower explosion limit: 30 g/m ³
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:	Practically insoluble in hot water. It dissolves in cold water giving a colloidal solution.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Observe technical data sheet.
Explosive properties:	Dust explosion hazard.
Oxidising properties:	Shall not be classified as oxidising.

9.2 Other information

Density: 1.26 - 1.31 g/cm³

Bulk density: > 0.2 g /cm³

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Acids, bases, peroxides, strong oxidisers.

10.4 Conditions to avoid

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



Take precautionary measures against static discharge.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

The product in the delivered form is not dust explosion capable; However, the enrichment of fine dust leads to the danger of dust explosion.

10.5 Incompatible materials

Oxidisers.

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Shall not be classified as acutely toxic. Oral LD50 (rat): > 4 000 mg/kg Oral LD50 (mouse): > 1 000 mg/kg
Skin corrosion/irritation:	Shall not be classified as corrosive/irritant to skin.
Serious eye damage/irritation:	Shall not be classified as seriously damaging to the eye or eye irritant.
Respiratory/skin sensitisation:	Shall not be classified as a respiratory or skin sensitiser.
Germ cell mutagenicity:	Shall not be classified as germ cell mutagenic.
Carcinogenicity:	Shall not be classified as carcinogenic.
Reproductive toxicity:	Shall not be classified as a reproductive toxicant.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Shall not be classified as a specific target organ toxicant (single exposure).
STOT-repeated exposure:	Shall not be classified as a specific target organ toxicant (repeated exposure).
Aspiration Hazard:	Shall not be classified as presenting an aspiration hazard.
Other:	Not available.

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.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity (acute): Based on available data, the classification criteria are not met.

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



LC50 (*Danio rerio*): > 1 000 mg/l (96h exposure time) (Method: OECD Guideline 203)

EC50 (bacteria): > 1 000 mg/l (48h exposure time) (Method: OECD Guideline 209)

12.2 Persistence and degradability

Biodegradation: Not readily biodegradable. Poorly biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Other adverse effects

Endocrine disrupting potential: Not listed.

Water hazard class - WHC (Wassergefährdungsklasse): 1 (Slightly hazardous to water)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulations.

Sewage disposal-relevant information: Do not empty into drains.

Waste treatment of containers/packaging: Handle contaminated packaging in the same way as the substance itself.

Remarks: Please consider the relevant national or regional provisions.

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

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

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



HYPROMELLOSUM

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

The cargo is not intended to be carried in bulk.

14.8 Additional transport information

Not subject to transport regulations.

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

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.

Material Safety Data Sheet

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

HYPROMELLOSUM

EN

FORM-06-14-01 (V00)

Page 10/9

Publication: 29/09/2021

Revision: 29/09/2021

Version: 00



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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department
FAC SECUNDUM ARTEM NV
info@magis-pharma.be