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

1.1 Product identifier

Product name: Hydroxyethylcellulose

Hydroxyethylcellulosum Hydroxyethylcellulose Hydroxyethylcellulose Hydroxyethylcellulose

N° CAS: 9004-62-0 N° EC: 618-387-5

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 a hazardous substance or mixture.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

Not applicable.

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: Hydroxyethylcellulose

IUPAC name: 5-[6-[[3,4-dihydroxy-6-(hydroxymethyl)-5-methoxyoxan-2-yl]oxymethyl]-3,4-

dihydroxy-5-[4-hydroxy-3-(2-hydroxyethoxy)-6-(hydroxymethyl)-5-methoxyoxan-2-

yl]oxyoxan-2-yl]oxy-6-(hydroxymethyl)-2-methyloxane-3,4-diol

Synonyms: HEC

Natrosol

N° CAS: 9004-62-0 N° EC: 618-387-5

Molecular Formula: Not available.

Content: 30.0 per cent to 70.0 per cent of hydroxyethoxy (-OC2H4OH) groups (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

Symptoms: The most important known symptoms and effects are described in the labelling (see section 2.2) and/or 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

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Suitable extinguishing media: Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Water spray.

Foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Specific hazards during firefighting: Organic dusts at sufficient concentration can form explosive mixtures in air. Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products: Carbon dioxide (CO_2), carbon monoxide, nitrogen oxides (No_x), oxides of phosphorus, sodium oxides.

5.3 Advice for firefighters

Surrounding fires: Specific extinguishing methods: 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. Material can create slippery conditions. Persons not wearing protective equipment should be excluded from are 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. Material can create slippery conditions. 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 and section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid breathing dust. The material can accumulate static charge and

can therefore cause electrical ignition of flammable atmospheres.

Smoking, eating and drinking should be prohibited in the application

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area. Maintain good housekeeping. Do not permit dust layers to

accumulate, for example, on floors, ledges, and equipment, in order

to avoid any potential for dust explosion hazards.

Personal protection: For personal protection, see section 8.

Technical protective measures: Avoid dust formation.

Ensure all equipment is electrically grounded and bonded before

beginning transfer operations.

Advice on protection against fire and explosion: 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: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep in a dry place. No decomposition if stored and applied as

directed. No smoking.

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

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.

Protective clothing complying with EN 13688. Safety shoes complying with EN ISO 20345

Hand protection: Material: butyl rubber

Breakthrough time: 480 min Glove thickness: > 0.5 mm

The exact breakthrough 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.

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

Odour:
Odourless.
Odourthreshold:
Not available.
pH:
Not available.
Melting/freezing point:
Not available.
Initial boiling point:
Not available.
Boiling range:
Not available.
Flash point:
Not applicable.

Upper/lower flammability or

Flammability (solid/gas):

explosive limits:

Evaporation rate:

Lower explosion limit: 30 g/m³

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

Solubility: Practically insoluble in acetone, in ethanol (96%) and in toluene.

Solubility in water: Soluble in hot and cold water giving a colloidal solution.

Partition coefficient

(n-octanol/water):

Not available.

Not available.
Not available.

Auto-ignition temperature: 460 °C

Decomposition temperature: Not available. Viscosity: Not available.

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Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Density: 1.38 g/cm³

Dust deflagration index (Kst): < 200 m.b_/s

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

Dust may form explosive mixture in air.

10.4 Conditions to avoid

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

UV light. Exposure to sunlight. Exposure to moisture.

10.5 Incompatible materials

Acids, bases, oxidising agents, strong bases.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide (CO₂), nitrogen oxides (No_x), oxides of phosphorus, sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified bases on available information.

Skin corrosion/irritation: Not classified bases on available information.

Serious eye damage/irritation: Not classified bases on available information.

Remarks: Unlikely to cause eye irritation or injury. Product dust may be irritating to

eyes, skin and respiratory system.

Respiratory/skin sensitisation: Not classified bases on available information.

Germ cell mutagenicity: Not classified bases on available information.

Carcinogenicity: Not classified bases on available information.

Reproductive toxicity: Not classified bases on available information.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not classified bases on available information.

STOT-repeated exposure: Not classified bases on available information.

Aspiration Hazard: Not classified bases on available information.

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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: Not readily biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB 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),

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)

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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 applicable.

IATA/ICAO (Air):

14.6 Special precautions for user

Not applicable.

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

Not applicable.

14.8 Additional transport information

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

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

European Agreement concerning the International Carriage of Dangerous Goods by ADR:

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: International Air Transport Association International Civil Aviation Organization ICAO:

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

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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

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