

Material Safety Data Sheet

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

EN

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MAGNESII STEARAS

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

1.1 Product identifier

Product name:	Magnesium stearate Magnesii stearas Magnesiumstearaat Magnésium (stéarate de) Magnesiumstearat
N° CAS:	91031-63-9
N° EC:	292-967-2

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 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

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Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Magnesium stearate
IUPAC name:	Magnesium;hexadecanoate;octadecanoate
Synonyms:	Fatty acids, C16-C18, magnesium salts Magnesium octadecanoate
N° CAS:	91031-63-9
N° EC:	292-967-2
Molecular Formula:	Not available.
Content:	Compound of magnesium with a mixture of solid organic acids and consisting mainly of variable proportions of magnesium stearate and magnesium palmitate obtained from sources of vegetable or animal origin. – magnesium (Mg; A _r 24.305): 4.0 per cent to 5.0 per cent (dried substance); – stearic acid in the fatty acid fraction: minimum 40.0 per cent; – sum of stearic acid and palmitic acid in the fatty acid fraction: minimum 90.0 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing immediately.
After inhalation:	Fresh air, rest. If necessary, seek medical advice.
After skin contact:	Wash skin with plenty of water and soap. If necessary, seek medical advice.
After eye contact:	Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Obtain emergency medical attention.
After ingestion:	Rinse mouth. Immediately consult a doctor/medical service.

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:	Carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media:	Do not use a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance/mixture

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Fire hazard: In case of fire, it can release carbon oxides (CO and CO₂).

Explosion hazard: Its dust is explosive with air.

Reactivity: Stable at normal conditions. See section 7.

5.3 Advice for firefighters

Surrounding fires:

Avoid (reject) fire-fighting water to enter environment.

Protection against fire:

Use a self-contained breathing apparatus and also a protective suit.
Dust production: dust mask with filter type P2.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

General measures: No naked flames, sparks, and do not smoke.

Protective equipment: Wear suitable protective clothing.

Emergency procedures: Mark out the contaminated area with signs and prevent access to unauthorized personnel.

Spill area may be slippery.

For emergency responders

General measures: No naked flames, sparks, and do not smoke.

6.2 Environmental precautions

Use appropriate container to avoid environmental contamination.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Vacuum with an equipment that avoids ignition risk. Provide the tank with earthing.

Other information: Not in groundwater, surface water or sewerage. Notify authorities if product enters sewers or public waters.

6.4 Reference to other sections

Reference to other sections (8, 13).

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Keep away from sources of ignition - No smoking. Avoid raising dust.
Do not eat, drink or smoke when using this product. Use only explosion-proof equipment.

Personal protection:

Not available.

Technical protective measures:

Avoid dust formation. Potential dust explosion hazard. Keep away from ignition sources.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

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Conditions for safe storage, including any incompatibilities:

Avoid dust formation. Prevent build-up of electrostatic charges (e.g. by grounding). Earth the equipment. Use spark-/explosion proof appliances and lighting system.

Store tightly closed in a dry and cool place. Exclude sources of heat, sparks and open flame.

Storage – away from:

Keep away from heat and direct sunlight. Keep away from ignition sources.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Provide appropriate exhaust ventilation at places of dust forming.

Individual protection measures

Eye/face protection: In case of risky circumstances: safety glasses or face shield

Skin protection: Wear suitable protective clothing.
Operators should wear anti-static footwear and clothing and floors should be electrically conductive.

Hand protection: Wear suitable gloves.

Respiratory protection: Where exposure through inhalation may occur from use, approved respiratory protection equipment is recommended. Dust production: dust mask with 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 or almost white, very fine, light powder, greasy to the touch.

Odour: Characteristic.

Odour threshold: Not available.

pH: Not available.

Melting/freezing point: $\approx 140^{\circ}\text{C}$

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

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Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Explosive limits : $\geq 30 \text{ g/m}^3$
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Practically insoluble in anhydrous ethanol.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Density: $\approx 1.03 \text{ g/ml}$

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable at normal conditions. See section 7.

10.2 Chemical stability

Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

Finely dispersed particles form explosive mixtures in air.

10.4 Conditions to avoid

Avoid formation of dust.

Ignition sources.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Stable at room temperature.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not classified.

LD₅₀ oral rat: $> 2000 \text{ mg/kg}$

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Skin corrosion/irritation:	Not classified (Lack of data).
Serious eye damage/irritation:	Not classified (Lack of data).
Respiratory/skin sensitisation:	Not classified (Lack of data).
Germ cell mutagenicity:	Not classified (Lack of data).
Carcinogenicity:	Not classified (Lack of data).
Reproductive toxicity:	Not classified (Lack of data).
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified (Lack of data).
STOT-repeated exposure:	Not classified (Lack of data).
Aspiration Hazard:	Not classified (Lack of data).
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

Not available.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Ecology - waste materials: Collect all waste in suitable and labelled containers and dispose according to local legislation.

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SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not regulated for transport.
IATA/ICAO (Air) :

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), No supplementary information available.
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 applicable.

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 available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

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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.

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

info@magis-pharma.be

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