Material Safety Data Sheet

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

MAGNESII CITRAS

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Version: 01

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

1.1 Product identifier

Product name:	Magnesium citrate Magnesii citras Magnesiumcitraat Magnésium (citrate de) Magnesiumcitrat
N° CAS:	3344-18-1
N° EC:	222-093-9

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 according to Regulation (EC) No 1272/2008.

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

Can form an explosive mixture of dust and air.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Magnesium citrate
IUPAC name:	Trimagnesium;2-hydroxypropane-1,2,3-tricarboxylate
Synonyms:	Trimagnesium citrate Magnesium dicitrate
N° CAS:	3344-18-1
N° EC:	222-093-9
Molecular Formula:	$Mg_3(C_6H_5O_7)_2$
Content:	15.0 per cent to 16.5 per cent of Mg (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a physician if you feel unwell. Show this safety data sheet to the doctor in charge.
After inhalation:	In case of inhalation, bring the victim into the fresh air.
After skin contact:	Rinse skin immediately with plenty of water.
After eye contact:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If easy to do, remove any contact lenses.
After ingestion:	Clean mouth with water and drink a lot of water afterwards.

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

Treatment: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, dry powder, foam, carbon dioxide (CO_2).
Unsuitable extinguishing media:	Strong water jet.

5.2 Special hazards arising from the substance/mixture

Specific fire fighting hazards: Do not use solid water stream as it may burst and spread fire. In case of fire, hazardous decomposition products are formed.

Hazardous combustion products: Carbon dioxide (CO_2), carbon monoxide.

5.3 Advice for firefighters

Surrounding fires:	Standard procedure for chemical fires. Use extinguishing agents appropriate for the local conditions and environment. In case of fire and/or explosion, avoid breathing fumes.
Protection against fire:	If necessary, wear a compressed air mask when fighting fires. Use personal protective equipment.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with eyes and skin. Avoid breathing dust. Ensure adequate ventilation, especially in confined spaces.

For emergency responders

Avoid contact with eyes and skin. Avoid breathing dust. Ensure adequate ventilation, especially in confined spaces.

6.2 Environmental precautions

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Use mechanical processing machines. Store in suitable closed containers for disposal. Clean contaminated surface thoroughly.

6.4 Reference to other sections

For personal protection, see section 8. For disposal instructions, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid formation of dust. Advice on protection against fire and explosion: Normal measures for preventive fire protection. Dust explosion class: St1
Personal protection:	For personal protection, see section 8. Avoid contact with eyes, skin and clothing.
Technical protective measures:	Not available.
Handling:	Use according to accepted rules and practices for industrial hygiene and safety. Wash hands before breaks and immediately after using the product.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In a non-metallic, airtight container.
Conditions for safe storage, including any incompatibilities:	Keep containers tightly closed in a dry, cool and well-ventilated place. No decomposition if stored and applied as directed.
Storage – away from:	Never let the product come into contact with water during storage.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain any components for which exposure values have been established.

8.2 Exposure controls

Appropriate engineering control

Ensure adequate ventilation.

Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Choose protective clothing according to the amount and concentration of the hazardous substance in the workplace.
Hand protection:	Choose gloves to avoid contact with chemicals based on the concentration and amount of the hazardous substance in the workplace. It is advisable to discuss the chemical resistance of the above mentioned special application safety gloves with the glove manufacturer.
Respiratory protection:	In case of dust or aerosol formation, use a respirator with an approved filter. Half-mask with a P2 dust filter (European Standard EN 143).
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, fine, slightly hygroscopic powder.
Odour:	Odourless.
Odour threshold:	Not relevant.
pH:	5.0 – 9.0 (concentration: 5 %)
Melting/freezing point:	> 200 °C, decomposition
Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	The product is not flammable.
Upper/lower flammability or explosive limits:	Lower explosive limit: 500 000 mg/m^3 Upper explosive limit: Not available.
Vapour pressure:	Not applicable.

Vapour density:	Not applicable.
Relative density:	1.7 – 2.0 (20 °C)
Solubility:	Practically insoluble in ethanol (96%). It dissolves in dilute hydrochloric acid.
Solubility in water:	Soluble in water: 200 g/L (25 °C)
Partition coefficient (n-octanol/water):	log Pow: -1.8 – -0.2
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	> 200 °C
Viscosity:	Not applicable.
Explosive properties:	Not applicable.
Oxidising properties:	No oxidising effect.

9.2 Other information

Bulk density: 400 - 800 kg/m^3

Molecular weight: 451.12 g/mol

Dust explosion class: St1

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions have been observed under normal conditions of use.

10.4 Conditions to avoid

Avoid dust formation. Avoid moisture.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

In case of fire/high temperatures, formation of dangerous/toxic vapours possible.

Carbon dioxide (CO_2).

Carbon monoxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: <u>Acute oral toxicity:</u>

LD50 (mouse): 5 400 mg/kg body weight

Method: Guideline test OECD 401

Test substance: Non-neutralised product

	Acute dermal toxicity: LD50 skin (rat, male and female): > 2 000 mg/kg body weight Test substance: Non-neutralised product
Skin corrosion/irritation:	Species: Rabbit Result: No skin irritation Information given based on data obtained from equivalent substances.
Serious eye damage/irritation:	Species: Rabbit Method: Guideline test OECD 405 Result: No eye irritation Information given based on data obtained from equivalent substances.
Respiratory/skin sensitisation:	Species: Guinea pig Method: Guideline test OECD 406 Result: Did not cause sensitisation in laboratory animals. Information given based on data obtained from equivalent substances.
Germ cell mutagenicity:	Genotoxicity in vitro Test type: Ames test Species: *Salmonella typhimurium* Concentration: 0.0 - 10 mg/plate Method: Mutagenicity (*Salmonella typhimurium* - reverse mutation test) Result: Negative Information given based on data obtained from equivalent substances. Assessment: In vitro tests showed no mutagenic effects. Genotoxicity in vivo Test type: in vivo test Species: Rat (male) Method of application: Oral Method: Guideline test OECD 475 Result: Negative Test substance: Non-neutralized product
Carcinogenicity:	Not classifiable as a human carcinogen.
Reproductive toxicity:	Not toxic for reproduction.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	No classification for toxicity by aspiration.
Other:	Repeated dose toxicity Species: Rat NOAEL: 8 000 mg/kg LOAEL: 16 000 mg/kg

Method of application: Oral
Exposure time: 10 d
Dose: 2, 4, 8, 16 g/kg bw/day
Test substance: Non-neutralised product

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

Fish toxicity

LC50 (*Oncorhynchus tshawytscha* (chinook salmon)): > 10 mg/L
Exposure time: 24 h
Test type: semi-static test
Information given based on data obtained from equivalent substances.

LC50 (*Leuciscus idus* (Goldenrod)): 440 mg/L
Exposure time: 48 h
Test type: static test
Test substance: non-neutralised product

Toxicity to daphnia and other aquatic invertebrates

EC50 (*Dreissena polymorpha*): > 50 mg/L
Exposure time: 48 h
Test type: static test
Method: No data available.
Information given based on data obtained from equivalent substances.

Toxicity to algae

NOEC (*Scenedesmus quadricauda* (green algae)): 425 mg/L
Exposure time: 8 d
Test type: static test
Test substance: Non-neutralised product
Method: No data available.

Toxicity to micro-organisms

TT (Pseudomonas putida): > 10 000 mg/L

Exposure time: 16 h

Test substance: Non-neutralised product

12.2 Persistence and degradability

Biodegradability: Biodegradation: 97 %.

Exposure time: 28 d

Method: OECD Test Guideline 301B

Test substance: Non-neutralised product

Readily biodegradable.

Biodegradation: 100 %, Information given based on data obtained from equivalent substances.

Physico-chemical removability: Readily biodegradable.

12.3 Bioaccumulative potential

Bioaccumulation: The product is miscible in water and readily biodegradable in both water and soil. Accumulation is not expected.

Partition coefficient: n-octanol/water: log pow: -1,8 – -0,2

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance is not considered to be persistent, bioaccumulating or toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

12.6 Other adverse effects

Additional ecological information: No ecotoxicological effects are known from this product.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: According to local and national regulations. Reuse, where possible, is preferable to disposal or incineration. According to the European Waste List, waste codes are not product-specific, but application-specific. Waste codes should be assigned by the user, based on the application for which the product was used.

Contaminated packaging: Empty containers should be taken to a licensed waste management facility for reuse or disposal. Dispose of as unused product.

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 applicable.

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

Not applicable for product as supplied.

14.8 Additional transport information

Not regulated as dangerous substance.

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 been carried out for this substance.

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 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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