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

1.1 Product identifier

N° CAS:

Product name: Calcium carbonate

Calcii carbonate
Calciumcarbonaat
Calcium (carbonate de)

Calciumcarbonat

471-34-1

N° EC: 207-439-9

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: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk 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 is classified as not hazardous.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

Not applicable.

Precautionary statements:

Not applicable.

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Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Calcium carbonate

IUPAC name: Calcium carbonate

Synonyms: Aragonite

Limestone

 N° CAS: 471-34-1 N° EC: 207-439-9 Molecular Formula: $CaCO_3$

Content: 98.5 per cent to 100.5 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position

comfortable for breathing.

After skin contact: After contact with skin, take off immediately all contaminated clothing, and wash

immediately with plenty of water.

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact

lenses, if present and easy to do. Continue rinsing.

After ingestion: Rinse mouth immediately and drink plenty of water.

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

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Suitable extinguishing media:

The product does not burn at itself. Use fire fighting measures that suit the environment. CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Suppress gases/vapours/mists with water spray jet. Do not allow

water used to extinguish fire to enter drains, ground or waterways.

Treat runoff as hazardous.

Protection against 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

Provide adequate ventilation. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid generation of dust.

For emergency responders

Provide adequate ventilation. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid generation of dust.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal. Clear contaminated areas thoroughly.

6.4 Reference to other sections

For information on disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid generation of dust.

Personal protection: Do not breathe dust.

Technical protective measures: Provide adequate ventilation.

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Keep container tightly closed in a cool, well-ventilated place.

Conditions for safe storage, including any

incompatibilities:

Storage temperature recommended: < 25 °C.

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Storage – away from: Protect from moisture.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

DNEL:

Long-term inhalative (systemic), workers: 10 mg/m³ Long-term inhalative (local), workers: 4.26 mg/m³ Long-term inhalative (systemic), consumer: 10 mg/m³ Long-term inhalative (local), consumer: 1.06 mg/m³

Long-term oral (repeated), consumer: 6.1 mg/kg body weight Short-term oral (acute), consumer: 6.1 mg/kg bod weight

PNEC:

Sewage treatment plant (STP): 100 mg/l

8.2 Exposure controls

Appropriate engineering control

Immediately remove any contaminated clothing, shoes or stockings. Use protective skin cream before handling the product. Wash hands and face before breaks and after work and take a shower if necessary.

Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Wear suitable protective clothing.

Hand protection: Wear suitable gloves. Suitable material: NBR (Nitrile rubber). Material thickness: 0.4

mm. Break through time: > 480 min.

Respiratory protection: Respiratory protection necessary at: dust formation. Wear a respirator conforming

to EN140 with Type A/P2 filter or better.

Thermal hazards: Not determined.

Environmental exposure control

Do not empty into drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white powder

Odour: Odourless.

Odour threshold: Not available.

pH: 8.5 – 9.5 (20 °C)

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Melting/freezing point: 885 °C (thermal decomposition)

Initial boiling point: Not available. Not available. Boiling range: Not available. Flash point: Not available. Evaporation rate: Flammability (solid/gas): Not available. Upper/lower flammability or Not available.

explosive limits:

Not available. Vapour pressure:

Vapour density: 2.71 g/cm3 (20 °C)

Relative density: Not available. Solubility: Not available.

Solubility in water: Practically insoluble in water (0.3% at 20 °C)

Partition coefficient

(n-octanol/water):

Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: 900 °C

Not available. Viscosity: **Explosive properties:** Not available. Not available. Oxidising properties:

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Thermal decomposition: Decomposition takes place from temperatures above: 825 °C. Remarks: The following decomposition products result from melting: Carbon dioxide.

10.2 Chemical stability

Stable when applying the recommended regulations for storage and handling (see section 7).

10.3 Possibility of hazardous reactions

Violent reaction with acid.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

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10.6 Hazardous decomposition products

Carbon dioxide (CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD50 (rat): > 6 450 mg/kg

Skin corrosion/irritation: Not irritating.
Serious eye damage/irritation: Not irritating.
Respiratory/skin sensitisation: Not sensitizing.

Germ cell mutagenicity: No experimental indications of in vivo mutagenicity exist.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the Not available.

CMR properties:

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

Not available.

Aspiration:

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish: LC50 (Oncorhynchus mykiss) (96 h): > 10 000 mg/l

Toxicity to daphnia in other aquatic invertebrates: EC50 (Daphnia magna) (48 h): > 1 000 mg/l

Toxicity to algae: NOEC (*Desmodesmus subspicatus*) (72 h): 75 mg/l EC50 (*Desmodesmus subspicatus*) (72 h): 289 mg/l

12.2 Persistence and degradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

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Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects

Further information on ecology: According to the present state of knowledge negative ecological effects are not expected.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal considerations: Dispose of waste according to applicable legislation.

Contaminated packaging: Consult the appropriate local waste disposal expert about waste disposal.

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

Not available.

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

Not available.

14.8 Additional transport information

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non-hazardous product within the meaning of transportation 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 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

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

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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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