Material Safety Data Sheet

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

LITHII CARBONAS

Publication: 10/07/2021
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Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Lithium carbonate Lithii carbonas Lithiumcarbonaat Lithium (carbonate de) Lithiumcarbonat
N° CAS:	554-13-2
N° EC:	209-062-5

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

Acute Tox. 4	H302
Eye Irrit. 2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Attention
Warning

Hazard statements:

H302	Harmful if swallowed.
H319	Causes serious eye irritation.

Precautionary statements:	
P301+P330+P312	IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Lithium carbonate
IUPAC name:	Dilithium;carbonate
Synonyms:	Dilithium carbonate Lithonate Lithobid
N° CAS:	554-13-2
N° EC:	209-062-5
Molecular Formula:	Li_2CO_3
Content:	98.5 per cent to 100.5 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Protection is needed for the First Aider.
After inhalation:	After inhalation move to fresh air. If shortness of breath occurs, support respiration and consult a physician.
After skin contact:	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and seek medical advice.
After eye contact:	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
After ingestion:	Do not induce vomiting. In case of consciousness, wash mouth with water and let drink some of water. Seek medical advice. Keep patient at rest.
Self-protection of the first aider:	For personal protection, see section 8.

4.2 Most important symptoms and effects, both acute and delayed

Circulatory collapse. Disorders of the nervous conduction system. Drowsiness. Blurred vision.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray or fog, foam, dry chemical powder, CO_2, dry sand.
Unsuitable extinguishing media:	No restrictions.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: poisonous gases/vapours.

5.3 Advice for firefighters

Surrounding fires:	Not available.
Protection against fire:	Wear self-contained breathing apparatus and fire protective equipment.
Hazardous combustion products:	Poisonous gases/vapours.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with skin, eyes and clothing.

For emergency responders

Avoid contact with skin, eyes and clothing.

6.2 Environmental precautions

Must not be released into sewers, drains or wells.

6.3 Methods and material for containment and cleaning up

Transfer large quantities into a container, rinse the rest with plenty of water.

6.4 Reference to other sections

For personal protection, see section 8.

For disposal considerations, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	For industrial hygiene measures, see section 8, Exposure controls / Personal protection.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. Keep container in a well-ventilated place.
Storage – away from:	Protect against humidity.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

International exposure limit: 0.1 mg/m^3

8.2 Exposure controls

Appropriate engineering control

Industrial Hygiene: The personal protective measure may be adapted appropriately when working in closed systems or under laboratory conditions. Regular cleaning of equipment, work area and clothing. Open handling at operator intervention points with local exhaust ventilation (e.g. down flow booths).

Internal working procedures available to personnel covering personal hygiene, standard cleaning, waste disposal and maintenance. Personnel instructed and trained, regular refresher training established. Double wardrobe must be available.

Individual protection measures

Eye/face protection:	Safety glasses (EN166).	
Skin protection:	Working clothes (EN 340).	
Hand protection:	Normal length chemical-mechanical resistant gloves (EN374/EN388).	
	Glove material:	Nitrile
	Breakthrough time:	> 480 min.
	Thickness:	0.4 mm
Respiratory protection:	Disposable fine dust protection mask (EN149) or reusable half mask (EN140). Filter: P3 (EN143).	
Thermal hazards:	Not determined.	

These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the officially tested permeation time.

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 powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	10.5 (Concentration: 5 g/l, Temperature: 20 °C)
Melting/freezing point:	732 °C
Initial boiling point:	1310 °C (decomposing)

Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	2.11 kg/dm^3 (Temperature: 20 °C)
Relative density:	Not available.
Solubility:	Practically insoluble in ethanol (96%).
Solubility in water:	Slightly soluble in water. 13.3 g/l (Temperature: 20 °C) 7.2 g/l (Temperature: 100 °C)
Partition coefficient (n-octanol/water):	Unknown.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Bulk Density 400 - 800 kg/m^3

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Not available.

10.3 Possibility of hazardous reactions

Materials to avoid: strong oxidizing agents, fluorine, earth alkali metals.

10.4 Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition.

10.5 Incompatible materials

For Incompatible materials, see subsection 7.2 ‘Conditions for safe storage, including any incompatibilities’.

10.6 Hazardous decomposition products

Carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD_{50} (rat): 525 mg/kg Information from other sources (e.g. literature) Inhalative LC_{50} (rat): > 2 g/m^3 (4h) Method: OECD 403 * 1987 * Acute Inhalation Toxicity Dermal LD_{50} (rat): > 2000 mg/kg Method: OECD 402 * 1987 * Acute Dermal Toxicity Oral LD_{50} (mouse): 531 mg/kg Information from other sources (e.g. literature)
Skin corrosion/irritation:	Skin (Species: rat) non irritant Method: OECD 404 * 2002 * Acute Dermal Irritation/Corrosion Skin (Species: rabbit) mildly irritant
Serious eye damage/irritation:	Eyes (Species: rat) irritant Method: OECD 405 * 2002 * Acute Eye Irritation/Corrosion
Respiratory/skin sensitisation:	Skin (Species: Animal) not sensitizing Method: OECD 406 * 1981 * Bühler Test
Germ cell mutagenicity:	Positive with metabolic activation in vitroCell: V79 cells (embryonic lung fibroblasts) of the Chinese hamster Positive (Micronucleus Test) in vivo, Species: mouse
Carcinogenicity:	The substance causes concern for man owing to possible carcinogenic effects, but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in OHC Category 3. Handling this substance, precautionary measures should be taken according to workplace health risk assessment.
Reproductive toxicity:	This substance has been shown to have unwanted effects on the reproductive system of both sexes. This substance has been shown to have unwanted effects on pregnancy and/or unborn/offspring. It is recommended that persons working with or around this substance are informed and their exposure evaluated according to local policies. Handling this substance, precautionary measures should be taken according to workplace health risk assessment. Male fertility decreased (Fertility and general reproductive performance study) NOAEL oral: 500 mg/kg/d Species: rat, Sex: male Embryo toxicity (Embryo-Foetal Development) Oral: 187.8 mg/kg/d Species: rat, Sex: female
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Pathological findings (Repeated Dose Toxicity) NOAEL oral: 34 ppm Species: rat, Organ: Liver, kidneys

	Duration: 12 weeks male
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Fish acute toxicity

LC_{50}: 30.3 mg/l
Species: rainbow trout (*Salmo gairdneri*, *Oncorhynchus mykiss*)
Exp. time: 96 hours
Method: OECD 203 * 1992 * acute toxicity

NOEC: 19.1 mg/l
Species: rainbow trout (*Salmo gairdneri*, *Oncorhynchus mykiss*)
Exp. time: 96 hours
Method: OECD 203 * 1992 * limit test

Aquatic invertebrate acute toxicity

EC_{50}: 33 mg/l
Species: *Daphnia magna* (water flea)
Exp. time: 48 hours
Method: OECD 202 * 1984 * Acute Immobilisation Test

NOEC: 20 mg/l
Species: *Daphnia magna* (water flea)
Exp. time: 48 hours
Method: OECD 202 * 1984 * Acute Immobilisation Test

Algae Toxicity

ErC_{50}: > 400 mg/l
Species: *Desmodesmus subspicatus*/*Scenedesmus subspicatus* (Green algae)
Exp. time: 72 hours
Method: OECD 201 * 2006

NOEC: 50 mg/l
Species: *Desmodesmus subspicatus*/*Scenedesmus subspicatus* (Green algae)
Exp. time: 72 hours
Method: OECD 201 * 2006

Bacterial Respiration Inhibition

EC_{50}: 278 mg/l
Species: activated sludge
Method: dried substance. OECD 209 * 1984.

12.2 Persistence and degradability

Not available.

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

Disposal Requirements: Local regulations should be adhered to.

Container Disposal: Empty containers can be disposed or re-used after cleaning, when in compliance with the environmental regulations (Duty of Care).

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) :	No dangerous good.

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 available.

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

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Not applicable.

15.2 Chemical safety assessment

Not required.

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

Quality Department

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