Material Safety Data Sheet

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

CALAMINA

Publication: 11/09/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Calamine Calamina Calamine Calamine Calamine
N° CAS:	8011-96-9
N° EC:	N/A

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

Aquatic Chronic 1	H410

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Attention

Hazard statements:

H410	Very toxic to aquatic life with long-lasting effects.

Precautionary statements:

P273	Avoid release to the environment.
P501	Dispose of contents/container in accordance with federal, state and local environmental control regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product name :	Zinc carbonate
IUPAC name:	Zinc;carbonate
Synonyms:	Zinc monocarbonate
	Carbonic acid, zinc salt (1:1)
N° CAS:	3486-35-9
N° EC:	222-477-6
Molecular Formula:	CO_3Zn
Content:	99.5%
Product name :	Hematite (Fe_2O_3)
IUPAC name:	Iron(3+); oxygen(2-)
Synonyms:	Iron(III)oxide
	Iron ore
N° CAS:	1317-60-8
N° EC:	215-275-4
Molecular Formula:	Fe_2O_3
Content:	0.5%

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
After skin contact:	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.
After eye contact:	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.
After ingestion:	

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Hazardous in case of inhalation. Slightly hazardous in case of skin contact (irritant), eye contact (irritant), ingestion.

Potential Chronic Health Effects

Mutagenic effects: Mutagenic for mammalian somatic cells, mutagenic for bacteria and/or yeast.

Developmental toxicity: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

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:	Not available.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

May explode when mixed with chlorinated rubber.

Zinc Oxide and Magnesium can react explosively when heated.

5.3 Advice for firefighters

Surrounding fires:	The product is non-flammable.
Protection against fire:	Not available.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

Not available.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep locked up. Do not ingest. Do not breathe dust. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label.
Personal protection:	Wear suitable protective clothing.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep container tightly closed. Keep container in a cool, well-ventilated area.
Conditions for safe storage, including any incompatibilities:	Do not store above 25°C (77°F).
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

Not available.

8.2 Exposure controls

Appropriate engineering control

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures

Eye/face protection:	Safety glasses. In case of a large spill: splash goggles.
Skin protection:	Lab coat. In case of a large spill: Full suit, boots. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Hand protection:	In case of a large spill: gloves.
Respiratory protection:	Dust respirator. Be sure to use an approved/certified respirator or equivalent. In case of a large spill: Dust respirator. A self contained breathing apparatus should be used to avoid inhalation of the product.
Thermal hazards:	Not determined.

Environmental exposure control

Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	An amorphous, impalpable, pink or reddish brown powder, the colour depending on the variety and amount of iron(III) oxide present and the process by which it is incorporated.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
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 applicable.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Soluble in dilute acetic acid or mineral acid, ammonia, ammonium carbonate, and fixed alkali hydroxide solution. It dissolves with effervescence in hydrochloric acid.
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

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

See section 10.3.

10.2 Chemical stability

The product is stable.

Corrosivity: Non-corrosive in presence of glass.

Polymerisation: Will not occur.

10.3 Possibility of hazardous reactions

Reacts violently with magnesium, linseed oil.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Not available.
Skin corrosion/irritation:	Slightly hazardous in case of skin contact (irritant). May cause mild skin irritation.
Serious eye damage/irritation:	May cause mechanical eye irritation and conjunctivitis.
Respiratory/skin sensitisation:	May cause digestive tract irritation although Zinc carbonate has a low toxicity by oral exposure route.
Germ cell mutagenicity:	Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast. May affect genetic material (mutagenic).
Carcinogenicity:	Not available.
Reproductive toxicity:	May cause adverse reproductive effects based on animal data. No human data found at this time.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Prolonged or repeated ingestion of zinc carbonate may affect blood, metabolism, and the thyroid.
Aspiration Hazard:	Not available.
Other:	Fume Fever: Symptoms of metal fume fever may include a flu-like condition involving headache, chills, fever, sweats, nausea, vomiting, cough, muscle aches and pains, and difficulty breathing; Pulmonary edema. May also affect the liver.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause mechanical eye irritation and conjunctivitis.

Skin contact:	Slightly hazardous in case of skin contact (irritant). May cause mild skin irritation.
Inhalation:	Hazardous in case of inhalation. May cause mechanical irritation of the respiratory tract. A few sources claim that finely divided zinc carbonate can cause "metal fume fever" Zinc carbonate is generally considered a nuisance dust; adverse effects are unlikely when exposures are kept under reasonable control.
Ingestion:	Slightly hazardous in case of ingestion. May cause digestive tract irritation although Zinc carbonate has a low toxicity by oral exposure route. Prolonged or repeated ingestion of zinc carbonate may affect blood, metabolism, and the thyroid.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

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

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

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 available.

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

Not available.

14.8 Additional transport information

Not a DOT controlled material.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Harmful to the environment.

Risk phrases: R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases: S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

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

Classification based on the main component.

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.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department
FAC SECUNDUM ARTEM NV
info@magis-pharma.be