Material Safety Data Sheet

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

ZINCI OXIDUM

Publication: 18/03/2022
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:	Zinc oxide Zinci oxidum Zinkoxide Zinc (oxyde de) Zinkoxid
N° CAS:	1314-13-2
N° EC:	215-222-5

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

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.
P391	Collect spillage.

P501	Dispose of the contents and packaging in accordance with local/regional/national/ international regulations.
Additional applicable label elements:	

2.3 Other hazards

Results of PBT and vPvB assessment: PBT: Not applicable. vPvB: Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Zinc oxide
IUPAC name:	Oxozinc
Synonyms:	Zinc white Zinc monoxide
N° CAS:	1314-13-2
N° EC:	215-222-5
Molecular Formula:	ZnO
Content:	99.0 per cent to 100.5 per cent (ignited substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove the victim from the danger zone and lay him down. Remove contaminated clothing immediately.
After inhalation:	Remove casualty to fresh air and lay down comfortably.
After skin contact:	If skin irritation continues, consult a doctor. Immediately wash with water and soap and rinse thoroughly.
After eye contact:	Rinse the eyes under running water for several minutes while keeping the eye socket open. If symptoms persist, consult a doctor.
After ingestion:	Rinse mouth and drink plenty of water. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Gastrointestinal complaints. Cough.

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:	Extinguishing powder. Adapt fire-fighting measures to the surrounding area.

Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

In case of heating or fire, toxic gases may be formed.

5.3 Advice for firefighters

Surrounding fires:	Cool the exposed containers with water spray. Collect the contaminated extinguishing water separately, do not allow it to reach the sewage system.
Protection against fire:	Wear respiratory protection equipment that is not dependent on the ambient air.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid dust formation. Ensure adequate ventilation. Use respiratory protective device against the effects of fumes/dust/aerosol. Keep away from ignition sources.

For emergency responders

Avoid dust formation. Ensure adequate ventilation. Use respiratory protective device against the effects of fumes/dust/aerosol. Keep away from ignition sources.

6.2 Environmental precautions

Do not allow to penetrate the ground/soil.

If penetrating sewage system or sewage system, inform the competent authority.

Do not allow to enter drainage system/surface water/groundwater.

6.3 Methods and material for containment and cleaning up

Carefully clean the accident site; are suitable for this purpose: Dilute with plenty of water.

6.4 Reference to other sections

Information on safe use - see section 7.

Information on personal protective equipment - see section 8.

Information on disposal - see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Keep tanks tightly sealed.
Personal protection:	Not available.
Technical protective measures:	Information about fire and explosion protection: No special measures required.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Requirements to be met by storerooms and tanks: No special requirements.

Conditions for safe storage, including any incompatibilities:	Store tank in a well-ventilated place. Protect against freezing.
Storage – away from:	Store separately from oxidising agents. Store separately from reducing agents. Store separately from metals. Keep away from foodstuffs.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with limit values that require monitoring at the workplace:

1314-13-2 zinc oxide

GW (BE) Short-term value: 10 mg/m^3
Long-term value: 5 mg/m^3
respirable fraction

DNEL's

Oral	DNEL Long-term - Systemic (consumer)	0.83 mg/kg bw/day (/)
Dermal	DNEL Long-term - Systemic (worker)	83 mg/kg bw/day (/)
	DNEL Long-term - Systemic (consumer)	83 mg/kg bw/day (/)
Inhalative	DNEL Long-term - Systemic (worker)	5 mg/m^3 (/)
	DNEL Long-term - Local (worker)	0.5 mg/m^3 (/)
	DNEL Long-term - Systemic (consumer)	2.5 mg/m^3 (/)

PNEC's

PNEC Fresh water	0.0206 mg/l (/)
PNEC Marine water	0.0061 mg/l (/)
PNEC Fresh water sediment	117.8 mg/kg (/)
PNEC Marine sediment	56.5 mg/kg (/)
PNEC Soil	35.6 mg/kg (/)
PNEC STP	0.1 mg/l (/)

Additional information: Lists valid at the time of compilation were used as a basis.

8.2 Exposure controls

Appropriate engineering control

Do not eat, drink or smoke when using. After handling, thoroughly cleanse the skin immediately. The usual precautionary measures for handling chemicals should be observed. Wash hands before breaks and at the end of work.

Individual protection measures

Eye/face protection:	EN 166.
Skin protection:	Wear suitable protective work clothing.

Hand protection:	Check protective gloves for compliance before each use. The glove material must be impermeable and resistant against the product/the substance/the preparation. No recommendation for the glove material for the product/the preparation/the chemical mixture can be made on the basis of failed tests. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
Glove material:	EN374 Nitrile rubber Recommended thickness of material: ≥ 0.11 mm The selection of a suitable glove does not only depend on the material, but also on other quality characteristics and varies from manufacturer to manufacturer.
Penetration time of glove material:	For the mixture of chemicals mentioned below, the penetration time has to be at least 480 minutes (permeation according to EN 374 Part 3: Level 6). The exact break trough time has to be found out by the manufacturer of the glove and has to be observed.
Respiratory protection:	Filter P2. 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:	Soft, white or faintly yellowish-white, amorphous powder, free from gritty particles.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	(100 g/l) at 20 °C: 7-8
Melting/freezing point:	1970 – 1975 °C
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	The substance is not flammable.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	Not applicable.
Vapour density:	Not applicable.
Relative density:	5.4 – 5.7 g/cm^3 (20 °C)
Solubility:	Practically insoluble in ethanol (96 per cent). It dissolves in dilute mineral acids.
Solubility in water:	Practically insoluble in water. 0.0029 g/l (Zn solubility) (20 °C)

Partition coefficient (n-octanol/water):	Not determined.
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
Viscosity:	Not applicable.
Explosive properties:	The product is not explosive.
Oxidising properties:	Not determined.

9.2 Other information

Molar mass: 81.38 g/mol

Density: 5.4 – 5.7 g/cm^3 (20 °C)

Bulk density: 300 – 2,000 kg/m^3

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not determined. No further relevant information available.

10.2 Chemical stability

Stable.

Thermal degradation/conditions to be avoided: No degradation if stored and handled as directed.

10.3 Possibility of hazardous reactions

Reactions with peroxides. Reactions with strong acids. Reactions with strong alkalis. Reactions with oxidizing agents. Reactions with aluminium.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong acids. Oxidising substances. Strong bases. Aluminium. Strong oxidising agents.

10.6 Hazardous decomposition products

Irritating gases/vapours. Toxic gases/vapours.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Based on available data, the classification criteria are not met.		
	Oral	LD50	> 5,000 mg/kg (rat) (OECD 401)
	Inhalation	LC50/4 h (Aerosol/Mist)	> 5.7 mg/l (rat) (OECD 403)
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.		
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.		
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.		
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.		
Carcinogenicity:	Based on available data, the classification criteria are not met.		
Reproductive toxicity:	Based on available data, the classification criteria are not met.		

Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
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

Aquatic toxicity:

EC 50 (72 h)	0.136 mg/l (*Selenastrum capricornutum*)
EC 50 (3 h)	5.2 mg/l (Activated Sludge)
NOEC	0.039 mg/l (*Oncorhynchus mykiss*) (30d)
	0.031 mg/l (*Daphnia magna*) (50d)
LC 50 (96 h) (static)	0.169 mg/l (*Oncorhynchus mykiss*)
EC 50 (48 h)	0.413 mg/l (*Ceriodaphnia dubia*)

12.2 Persistence and degradability

Inorganic product, cannot be eliminated from the water by the biological cleaning process.

12.3 Bioaccumulative potential

Does not accumulate in organisms.

12.4 Mobility in soil

No further relevant information available.

Remark: Very toxic for fish.

General information: Water hazard class 3 (D) (Self-assessment): hazardous for water. Do not allow to enter ground water, surface water or sewage system, even in small quantities. Danger to drinking water even if very small quantities leak into the ground. In surface water also poisonous for fish and plankton. very toxic for aquatic organisms.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation: Must not be disposed of together with household rubbish.

Uncleaned packagings: Recommendation: Non-contaminated packaging can be recycled.

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) :	UN3077

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	ADR/RID: 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT IATA: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	9

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	III

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Marine pollutant: yes.

14.6 Special precautions for user

Warning: Various dangerous substances and objects.

Kemler number:	90
EMS number:	F-A,S-F
Stowage Category	A
Stowage Code	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

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

Not applicable.

14.8 Additional transport information

ADR/RID

Limited quantities (LQ):	5 kg
Excepted quantities (EQ):	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
Transport category:	3

IMDG

Limited quantities (LQ):	5 kg
Excepted quantities (EQ):	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
VN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9, III

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 sheets.

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

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