

Material Safety Data Sheet

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

EN

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SILICA COLLOIDALIS HYDRICA

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

1.1 Product identifier

Product name:	Silica, colloidal hydrated Silica colloidalis hydrica Colloïdaal siliciumdioxide, waterhoudend Silice colloïdale hydratée Siliciumdioxid-Hydrat
N° CAS:	63231-67-4
N° EC:	231-545-4

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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.centreatipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

This substance is not classified as dangerous 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

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Effects on the environment: As it is, this product does not present any specific environmental hazard.

Physico-chemical hazards: No particular risk of ignition or explosion.

Diverse: Results of PBT and vPvB assessments: inorganic. Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Silica, colloidal hydrated
IUPAC name:	Dihydroxy(oxo)silane
Synonyms:	Silica gel Synthetic Amo Silica
N° CAS:	63231-67-4
N° EC:	231-545-4
Molecular Formula:	SiO ₂
Content:	98.0 per cent to 100.5 per cent of SiO ₂ (M, 60.1) (ignited substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Remove contaminated clothing, brush and wash separately.
After inhalation:	Remove the subject from the contaminated area, provide fresh air. Blow nose. In case of persistent symptoms: Consult a doctor. If Strong inhalation of dust: Remove the subject to fresh air, have him/her rinse his/her throat thoroughly with drinking water.
After skin contact:	Wash immediately, abundantly and for a long time with water and soap.
After eye contact:	Immediately wash with plenty of water for a prolonged period. If irritation persists, consult an ophthalmologist.
After ingestion:	In case of trouble: Consult a physician.
Self-protection of the first aider:	If a possibility of exposure exists, consult Section 8 for specific personal protective equipment.

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:	Non-combustible product, use appropriate means to fight nearby fires.
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Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

None.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: In case of 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

Avoid inhalation of dust.

Avoid crushing of the product, formation and diffusion of dust in the atmosphere.

For emergency responders

Avoid inhalation of dust.

6.2 Environmental precautions

Do not allow product to reach sewage system.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Pick up and dispose of without creating dust. Sweep up and remove with a shovel. Keep in suitable, closed containers for disposal.

Disposal: See section 13.

6.4 Reference to other sections

None.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Do not eat, smoke or drink in the work area.

Personal protection: Not available.

Technical protective measures: Provide water stations and eyewash fountains nearby.

Handling: Hygiene measures: Immediately remove all soiled or splashed clothing. Wash clothes in a special washing machine. Immediately wash all affected parts of the body. See section 4.

Wash hands after handling. Remove contaminated clothing and protective equipment before entering a food service area.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed in a dry, well-ventilated place.

Packaging material: Recommended: Plastic bags.

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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

Exposure limit values (dust)

Source	Date	Type of value	Value (mg/m ³)	Remarks
INRS (FR)	01 2008	VME	5	Respiratory fraction. Binding regulatory value.
INRS (FR)	01 2008	VME	10	Inhalable fraction. Binding regulatory value.
ACGIH (US)	02 2012	TWA	10	Inhalable particles.
ACGIH (US)	02 2012	TWA	3	Respirable dust.

Exposure limit values

Amorphous silica

Source	Date	Type of value	Value (mg/m ³)	Remarks
OSHA Z3 (US)	2000	TWA	20 millions of particles per cubic foot of air	-
OSHA Z3 (US)	2000	TWA	0.8	80/(%SiO ₂), using a value of 100% SiO ₂ .

Derived No Effect Level (DNEL)

Workers, inhalation: 4 mg/m³

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Safety glasses, eye wash bottle with pure water.

Skin protection: Protective clothing.

Hand protection: Impervious gloves.

Respiratory protection: Dust mask recommended.

Thermal hazards: Not determined.

Environmental exposure control

See section 6.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

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Appearance:	White or almost white, light, fine, amorphous powder.
Odour:	None.
Odour threshold:	Not available.
pH:	4.0 to 7.0
Melting/freezing point:	> 1.700 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not applicable.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Practically insoluble in mineral acids, with the exception of hydrofluoric acid. It dissolves in hot solutions of alkali hydroxides.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not applicable, inorganic.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Apparent density: approx. 200 kg/m³

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

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Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

None.

SECTION 11: TOXICOLOGICAL INFORMATION

All available data on this product and/or the components listed in section 3 and/or analogous substances/metabolites have been taken into account for the hazard assessment.

11.1 Information on toxicological effects

Acute toxicity:

Inhalation

In animals: No mortality/4 hr/Rat: 2.08 mg/L (Method: OECD guideline 403), Local respiratory tract irritation, Eye irritation (Dust).

Ingestion

In animals: No mortality/Rat: 5 g/kg (Method: OECD Guideline 401)

Dermal

In animals: No mortality/Rabbit: 5 g/kg (Method: OECD guideline 402)

Skin corrosion/irritation:

In animals: No skin irritation (OECD Guideline 404, Rabbit, Exposure time: 4 h)

Serious eye damage/irritation:

In animals: Mild eye irritation (OECD Guideline 405, Rabbit)

Respiratory/skin sensitisation:

Skin contact, in humans: No effects reported in humans in industrial settings.

Germ cell mutagenicity:

Not genotoxic.

In vitro

Ames test: Inactive (Method: OECD Test Guideline 471)

In vitro CHO cell chromosome aberration test: Inactive (Method: OECD Test Guideline 473)

In vitro mammalian cell gene mutation test: Inactive (Method: OECD Test Guideline 476)

In vivo

In vivo rat micronucleus test: negative (Method: OECD Guideline 475)

Carcinogenicity:

In animals: No carcinogenic effects (Method: OECD Guideline 453, 2 years, Dietary) (Rat) (Mouse)

Reproductive toxicity:

Fertility

In animals: Repeated administration: No reproductive toxicity
NOAEL (Parental Toxicity): > 4 g/kg
(Rat, Dietary)

Foetal development

In animals: Exposure during pregnancy: No foetal developmental toxicity.
NOAEL (Developmental Toxicity): ≥ 1.35 g/kg
NOAEL (Maternal Toxicity): ≥ 1.35 g/kg
(Method: OECD Guideline 414, rat, rabbit, hamster, mouse, Oral)

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Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Inhalation

Inhalation of dust: Irritating to eyes and respiratory tract.

In animals: Inhalation: Inflammation, Sites of action: lung, NOAEL= 0.001 mg/L (Method: OECD Guideline 413, Rat, 3 months) (Dust)

Dietary: No general adverse effects observed.

NOAEL= 4g/kg bw/d (Method: OECD Guideline 408, Rat, 3 months)

STOT-repeated exposure: Not available.

Aspiration Hazard: Not applicable.

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

Ecotoxicological evaluation: All available and relevant data on this product and/or the components listed in section 3 and/or analogous substances/metabolites have been taken into account for the hazard assessment.

12.1 Toxicity

Fish

Not harmful to fish.

LC50, 96 h (*Danio rerio* (zebrafish)): > 10,000 mg/L (Method: OECD guideline 203)

Aquatic invertebrates

Not harmful to Daphnia.

EC50, 24 h (*Daphnia magna* (Large Daphnia)): > 1,000 mg/L (Method: OECD Guideline 202)

Aquatic plants

Not harmful to algae.

Can be considered as similar to a related product with experimental results: EC50r, 72 h (*Desmodesmus subspicatus* (green algae)): > 10,000 mg/L (Method: OECD Guideline 201)

12.2 Persistence and degradability

Biodegradation (in water): Methods for determining biodegradability are not valid for inorganic substances.

12.3 Bioaccumulative potential

Not applicable, inorganic.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

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Not applicable, inorganic.

12.6 Other adverse effects

None to our knowledge.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal of the product: In accordance with local and national 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 dangerous in the sense of transport 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

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None.

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 Bioaccumulative

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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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
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