

# Material Safety Data Sheet

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

EN

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Publication: 24/07/2023

Revision: XX/XX/XXXX

Version: 00



## SILICA COLLOIDALIS ANHYDRICA

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

#### 1.1 Product identifier

Product name:	Silica, colloidal anhydrous Silica colloidalis anhydrica Watervrij colloïdaal silicium Silice colloïdale anhydre Siliciumdioxid, Hochdisperses
N° CAS:	7631-86-9
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.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Not a hazardous substance according to Regulation (EC) 1272/ 2008 (CLP), its various amendments and adaptations and Directive 67/ 548/ EEC.

#### 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.

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### 2.3 Other hazards

None.

Principle routes of exposure:

Eye contact:

Skin contact:

Inhalation:

Ingestion:

Carcinogenicity:

Target organ effects:

Medical conditions aggravated by exposure:

Potential environmental effects:

Inhalation, skin contact, eye contact.

May cause mechanical irritation. Avoid contact with eyes.

May cause mechanical irritation and skin drying. Avoid contact with skin. No cases of sensitisation in humans have been reported.

Dust may be irritating to respiratory tract. Provide appropriate exhaust ventilation at machinery and at places where dust can be generated. See also section 8.

Adverse health effects are not expected. See section 11.

Does not contain any substances greater than 0.1% listed by IARC (International Agency for Research on Cancer), NTP (National Toxicology Program), OSHA (Occupational Safety and Health Administration), ACGIH (American Conference for Governmental Industrial Hygienists) or EU (European Union). See also section 11.

Lungs, see section 11

Asthma, Respiratory disorder.

None known. See section 12.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name: Silica, colloidal anhydrous

IUPAC name: Dioxosilane

Synonyms: Silicon dioxide  
Quartz

N° CAS: 7631-86-9

N° EC: 231-545-4

Molecular Formula: SiO<sub>2</sub>

Content: 99.0 per cent to 100.5 per cent of SiO<sub>2</sub> (ignited substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation: If cough, shortness of breath or other breathing problems occur, move to fresh air. Seek medical attention if symptoms persist. If necessary, restore normal breathing through standard first aid measures.

After skin contact:

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After eye contact:	Wash thoroughly with soap and water. Seek medical attention if symptoms develop.
After ingestion:	Flush eyes immediately with large amounts of water for 15 minutes. Seek medical attention if symptoms develop. Do not induce vomiting. If conscious, give several glasses of water. Never give anything by mouth to an unconscious person.

### 4.2 Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described in section 2 and/or in section 11.

### 4.3 Indication of any immediate medical attention and special treatment needed

Note to physicians: Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Silica is non-combustible, therefore no extinguishing media needs to be identified.
Unsuitable extinguishing media:	None.

### 5.2 Special hazards arising from the substance/mixture

Specific hazards arising from the chemical: None.  
Hazardous combustion products: None.

### 5.3 Advice for firefighters

Surrounding fires:	Risk of dust explosion: Not applicable.
Protection against fire:	Wear suitable protective equipment. In the event 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 dust formation.  
Ensure adequate ventilation.  
Use personal protective equipment.  
See also section 8.

#### For emergency responders

Use personal protection recommended in section 8.

### 6.2 Environmental precautions

Contain spilled product on land, if possible.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

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Methods for cleaning up: Clean up promptly by vacuum. Use of a vacuum with high efficiency particulate air (HEPA) filtration is recommended. Do not create a dust cloud by using a brush or compressed air. Pick up and transfer to properly labelled containers. See section 13.

### 6.4 Reference to other sections

See section 8 for more information. See section 13 for more information.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust. Provide appropriate exhaust ventilation at machinery and at places where dust can be generated. Do not create a dust cloud by using a brush or compressed air.

Personal protection:

Not available.

Technical protective measures:

Take precautionary measures against static discharges. All metal parts of the mixing and processing equipment must be earthed/grounded. Ensure all equipment is electrically earthed/grounded before beginning transfer operations. Fine dust is capable of penetrating electrical equipment and may cause electrical shorts. Provide appropriate exhaust ventilation at machinery and at places where dust can be generated. Do not create a dust cloud by using a brush or compressed air.

Handling:

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep containers tightly closed in a dry and well-ventilated place. Store at ambient conditions.

Keep in properly labelled containers.

Storage – away from:

Do not store together with volatile chemicals as they may be adsorbed onto product.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Exposure guidelines:

The table below is a summary. Please see the specific legislation for complete information.

Amorphous Silica, The regulatory exposure limits are found under the general silica, CAS RN 7631-86-9:

Australia:	2 mg/m <sup>3</sup> , TWA, Respirable
Austria MAK:	4 mg/m <sup>3</sup> , TWA, Inhalable fraction
Finland:	5 mg/m <sup>3</sup>

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Dust, or particulates not otherwise specified:	Germany TRGS 900:	4 mg/m <sup>3</sup> , TWA, Inhalable fraction
	India:	10 mg/m <sup>3</sup> , TWA
	Ireland:	2.4 mg/m <sup>3</sup> , TWA, Respirable dust
	Norway:	1.5 mg/m <sup>3</sup> , TWA, Respirable dust
	Switzerland:	4 mg/m <sup>3</sup> , TWA
	UK WEL:	6 mg/m <sup>3</sup> , TWA, Inhalable fraction 2.4 mg/m <sup>3</sup> , TWA, Respirable fraction
	US OSHA PEL:	6 mg/m <sup>3</sup> (54 FR2701)
	Belgium:	10 mg/m <sup>3</sup> , TWA, Inhalable 3 mg/m <sup>3</sup> TWA, Respirable
	China:	8 mg/m <sup>3</sup> , TWA 10 mg/m <sup>3</sup> , STEL
	France:	10 mg/m <sup>3</sup> , TWA Inhalable dust 5 mg/m <sup>3</sup> , TWA Respirable dust
	Italy:	10 mg/m <sup>3</sup> , TWA, Inhalable 3 mg/m <sup>3</sup> , TWA, Respirable
	Malaysia:	10 mg/m <sup>3</sup> , TWA, Inhalable 3 mg/m <sup>3</sup> , TWA, Respirable
	Spain:	10 mg/m <sup>3</sup> , VLA, Inhalable 3 mg/m <sup>3</sup> , VLA, Respirable
	US ACGIH - PNOS:	10 mg/m <sup>3</sup> , TWA, Inhalable 3 mg/m <sup>3</sup> , TWA, Respirable
	US OSHA - PEL:	15 mg/m <sup>3</sup> , TWA, Total dust 5 mg/m <sup>3</sup> , TWA, Respirable
	Derived No Effect Level (DNEL):	As required under the EU Registration, Evaluation and Authorization of Chemicals (REACH) Regulation, the Synthetic Amorphous Silica REACH Consortium developed a Derived No Effect Level (DNEL) for Synthetic Amorphous Silica of 4 mg/m <sup>3</sup> inhalable (Germany TRGS 900 occupational exposure limit).
	Predicted No Effect Concentration (PNEC):	Not applicable.

### 8.2 Exposure controls

#### Appropriate engineering control

Ensure adequate ventilation to maintain exposures below occupational limits. Provide appropriate local exhaust ventilation at machinery and at places where dust can be generated.

Handle in accordance with good industrial hygiene and safety practice. Emergency eyewash and safety shower should be located nearby.

#### Individual protection measures

Eye/face protection: Wear eye/ face protection. Wear safety glasses with side shields (or goggles).

Skin protection: Wear suitable protective clothing. Wash clothing daily. Work clothing should not be allowed out of the workplace.

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**Hand protection:** Wear protective gloves to prevent skin drying. Use protective barrier cream before handling the product. Wash hands and other exposed skin with mild soap and water.

**Respiratory protection:** Approved respirator may be necessary if local exhaust ventilation is not adequate.

**Thermal hazards:** Not determined.

### **Environmental exposure control**

In accordance with all local legislation and permit requirements as applicable for dusts.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, light, fine, amorphous powder, with a particle size of about 15 nm.
Odour:	None.
Odour threshold:	Not applicable.
pH:	3.6 – 4.5
Melting/freezing point:	1700 °C
Initial boiling point:	2230 °C
Boiling range:	Not available.
Flash point:	Not combustible.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	Not flammable. Product resists ignition and does not promote flame spread.
Upper/lower flammability or explosive limits:	Not applicable.
Vapour pressure:	Not applicable.
Vapour density:	Not applicable.
Relative density:	2.2 g/cm <sup>3</sup> (20 °C)
Solubility:	Practically insoluble in mineral acids except hydrofluoric acid. It dissolves in hot solutions of alkali hydroxides.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not applicable.
Auto-ignition temperature:	Not applicable.
Decomposition temperature:	Not applicable.
Viscosity:	Not applicable.
Explosive properties:	Non-explosive.
Oxidising properties:	No oxidizing properties.

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### 9.2 Other information

Bulk density: 30 – 150 kg/m<sup>3</sup>

Specific gravity at 20 °C: 2.2

End point is listed "not applicable" due to the inherent properties of the substance. "No information available" indicates testing has not been performed.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not reactive. Substance is an inert inorganic solid.

### 10.2 Chemical stability

Stable under recommended handling and storage conditions.

#### Explosion data

Sensitivity to mechanical impact: None.

Sensitivity to static discharge: This material is an inorganic dust and will not create nor support conditions that would result in a dust explosion or fire. Take precautionary measures against static discharges. Avoid dust formation. All metal parts of the mixing and processing equipment must be earthed/ grounded. Ensure all equipment is electrically earthed/ grounded before beginning transfer operations.

### 10.3 Possibility of hazardous reactions

Hazardous polymerization: Hazardous polymerization does not occur.

Possibility of hazardous reactions: None under normal processing.

### 10.4 Conditions to avoid

None known.

### 10.5 Incompatible materials

None known.

### 10.6 Hazardous decomposition products

None known.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:

Oral LD<sub>50</sub>: LD<sub>50</sub>/oral/rat = > 5000 mg/ kg. No deaths occurred and no signs of toxicity were seen during the observation periods after single oral administration of silica (OECD 401).

Inhalation LD<sub>50</sub>: Due to the product's physical characteristics, no suitable testing procedure is available

Dermal LD<sub>50</sub>: LD<sub>50</sub>/dermal/rabbit = > 2000 mg/ kg Very slight transient erythema in one animal. No signs of systemic or organ toxicity (OECD 402).

Skin corrosion/irritation:

Primary irritation index = 0/8 @ 24 hr. Not classified as an irritant (OECD 404).

Serious eye damage/irritation:

Draize score 1.0/110 @ 24 hr. Not classified as an irritant in rabbit studies (OECD 405). High dust concentrations may cause mechanical irritation.

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Respiratory/skin sensitisation:	No experimental animal data are available. No cases of sensitization in humans have been reported.
Germ cell mutagenicity:	Not mutagenic in Ames test. Negative in the unscheduled DNA synthesis assay. Negative in the chromosome aberration test in Chinese hamster ovary (CHO) cells.
Carcinogenicity:	No evidence of carcinogenicity was observed in multiple animal species following repeated oral or inhalation exposure to amorphous silica. Similarly, epidemiology studies show no evidence of carcinogenicity in workers who manufacture amorphous silica.
Reproductive toxicity:	No effects on reproductive organs or foetal development have been reported in animal toxicity studies.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, specific target organ toxicity is not expected after single oral, single inhalation, or single dermal exposure.
STOT-repeated exposure:	Repeated dose toxicity: oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet. Repeated dose toxicity: inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) = 1.3 mg/ m <sup>3</sup> based on mild reversible effects in the lungs. Repeated dose toxicity: inhalation (rat), 90 days, LOEL = 1 mg/m <sup>3</sup> based on reversible effects in the lungs and effects in the nasal cavity. Based on available data, a STOT-RE classification is not warranted.
Aspiration Hazard:	Based on industrial experience and available data, no aspiration hazard is expected.
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:  
Fish (*Brachydanio rerio*) LC<sub>50</sub> (96 h): > 10,000 mg/L; (Method: OECD 203).  
No acute toxicity to Daphnia with EL and EL<sub>50</sub> ranging from >1000 to 10,000 mg/L (OECD 202).

### 12.2 Persistence and degradability

The methods for determining biodegradability are not applicable to inorganic substances.

### 12.3 Bioaccumulative potential

Not expected due to physicochemical properties of the substance.



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### 12.4 Mobility in soil

Mobility: Not expected to migrate.

### 12.5 Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).

This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Waste from residues/unused products: Disposal should be in accordance with applicable regional, national and local laws and regulations.

Disclaimer: Information in this section pertains to the product as shipped in its intended composition as described in section 3 of this MSDS. Contamination or processing may change waste characteristics and requirements.

Regulations may also apply to empty containers, liners or rinsate. State/ provincial and local regulations may be different from federal regulations.

## SECTION 14: TRANSPORT INFORMATION

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not regulated.  
IATA/ICAO (Air) :

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not available.  
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.

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### 14.8 Additional transport information

Not available.

## 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

EU Chemical Safety Assessment: Per Article 14.1 of the REACH Regulation, a Chemical Safety Assessment has been carried out.

EU Exposure Scenarios: Per Article 14.4 of the REACH Regulation, no exposure scenario has been developed as the substance is not hazardous.

## 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.

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### 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

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