

Safety Data Sheet

according to Regulation (EU) 2020/878, Annex II of the Reach Regulation (EC) No 1907/2006

Silicagel Trockenperlen Orange 1-3 mm

Revision date: 25.01.2024 Product code: 100873 Page 1 of 9

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Silicagel Trockenperlen Orange 1-3 mm

Further trade names

SII ICA

Substance name: amorphous silica

REACH Registration Number: 01-2119379499-16-XXXX

CAS No: 7631-86-9 EC No: 231-545-4

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Pharmaceutical production

1.3. Details of the supplier of the safety data sheet

Company name: VMP Chemiekontor GmbH

Street: Industriestr. 16
Place: D-53721 Siegburg

Telephone: 02241 / 26566-0 Telefax: 02241 / 26566-99

E-mail: vmp@vmp-chemiekontor.de

Contact person: QM-Abteilung

Internet: www.vmp-chemiekontor.de

1.4. Emergency telephone 02241 / 26566-0

<u>number:</u> Only available during office hours.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This substance is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

2.3. Other hazards

This substance/mixture does not contain any components, at concentrations of 0.1% or higher, that are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (VPVR)

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical characterization

SILICA

Sum formula: O2Si (Hill)
Molecular weight: 60,09



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Relevant ingredients

CAS No	Chemical name			Quantity
	EC No Index No REACH No			
	Classification (Regulation (EC) No 1272/2008)			
7631-86-9	amorphous silica			95-100 %
	231-545-4		01-2119379499-16-XXXX	

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
7631-86-9	231-545-4	amorphous silica	95-100 %
	inhalation: LC50 = < 2,19 mg/l (dusts or mists); dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 5000 mg/kg		

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

When in doubt or if symptoms are observed, get medical advice.

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eves

Rinse immediately carefully and thoroughly with eye-bath or water. In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Remove contact lenses.

After ingestion

Rinse mouth immediately and drink 1 glass of of water. Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

The most important known symptoms and effects are described on the label (see section 2.2) and/or in chapter 11.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Suitable extinguishing media: Carbon dioxide (CO2). Water spray jet alcohol-resistant foam. Water spray jet

Unsuitable extinguishing media

There are no extinguishing agent restrictions for this substance/mixture.

5.2. Special hazards arising from the substance or mixture

Non-flammable. Formation of hazardous vapours possible due to ambient fire.



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5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Suppress gases/vapours/mists with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Do not breathe dust. Provide adequate ventilation.

6.2. Environmental precautions

No special measures are necessary.

6.3. Methods and material for containment and cleaning up

For cleaning up

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

Other information

Avoid dust formation. Provide adequate ventilation.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid dust formation. Provide adequate ventilation.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately. Do not breathe dust. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. None known

Hints on joint storage

Store separately from food.

Further information on storage conditions

Keep container tightly closed and dry.

7.3. Specific end use(s)

Pharmaceutical production

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.



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8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection. Tight-fitting safety goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Wear protective gloves.

Thickness of the glove material NBR (Nitrile rubber): > 0,11 mm

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Breakthrough time:

Skin protection

Use of protective clothing. Protective clothing

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at: dust formation Filtering device with filter or ventilator filtering device of type: P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid Colour: white Odour: odourless

not determined Melting point/freezing point: Boiling point or initial boiling point and 2230 °C

boiling range:

Flammability: not determined Lower explosion limits: not determined Upper explosion limits: not determined Flash point: not applicable Auto-ignition temperature: not determined Decomposition temperature: not determined 3,7-4,7 pH-Value (at 25 °C): Viscosity / kinematic: not applicable Water solubility: The study does not need to be conducted because the substance is known to be

insoluble in water.

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined Vapour pressure: not determined Density: not determined Relative density (at 20 °C): 2.2 Bulk density (at 20 °C): 200-800 kg/m³ not determined Relative vapour density: not determined Particle characteristics:

9.2. Other information

Information with regard to physical hazard classes



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Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate: No information is available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

No decomposition when used as intended.

10.3. Possibility of hazardous reactions

Exothermic reaction with: Hydrogen halide, Sodium, Xenon hexafluoride.

10.4. Conditions to avoid

No information is available.

10.5. Incompatible materials

Strong acid

10.6. Hazardous decomposition products

In case of fire: see chapter 5

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Based on available data, the classification criteria are not met.

The substance is classified as not hazardous according to Directive 67/548/EEC.

The usual precautionary measures when handling chemicals must be observed.

CAS No	Chemical name	Chemical name				
	Exposure route	Dose		Species	Source	Method
7631-86-9	amorphous silica	amorphous silica				
	oral	LD50 mg/kg	> 5000	Rat	Study report (1999)	OECD Guideline 401
	dermal	LD50 mg/kg	> 2000	Rabbit	Review article or handbook (2006)	other: Guidelines of the Department of T
	inhalation (4 h) dust/mist	LC50 mg/l	< 2,19	Rat	Study report (1981)	1 dose level, 4 h administration, 14 d p

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Has degreasing effect on the skin.

Sensitising effects

Based on available data, the classification criteria are not met.

None known

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.



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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.

Eye irritation

Inhalation of dust may cause irritation of the respiratory system.

11.2. Information on other hazards

Endocrine disrupting properties

The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

Other information

The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

The product is not: Ecotoxic.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] [d]	Species	Source	Method
7631-86-9	amorphous silica						
	Acute fish toxicity	LC50 mg/l	> 5000	96 h	Pimephales promelas	REACh Registration Dossier	OECD Guideline 203
	Acute algae toxicity	ErC50 mg/l	> 173,1	72 h	Desmodesmus subspicatus	REACh Registration Dossier	OECD Guideline 201
	Acute crustacea toxicity	EC50 mg/l	> 5000	48 h	Daphnia magna	Study report (1998)	OECD Guideline 202
	Fish toxicity	NOEC mg/l	86,03	30 d	Fish species	http://epa.gov/oppt /exposure/pubs/ep isui	other: QSAR
	Crustacea toxicity	NOEC	68 mg/l	21 d	Daphnia magna	REACh Registration Dossier	OECD Guideline 211
	Acute bacteria toxicity	EC50 mg/l ()	> 2500	3 h	activated sludge of a predominantly domestic sewag	REACh Registration Dossier	OECD Guideline 209

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
7631-86-9	amorphous silica	0,53

BCF

CAS No	Chemical name	BCF	Species	Source
7631-86-9	amorphous silica	3,162	QSAR model	http://epa.gov/oppt/



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12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

This substance/mixture does not contain any components, at concentrations of 0.1% or higher, that are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

12.6. Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms. The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled. Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land	transport	(ADR/RID)
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14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

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14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of these transport regulations.



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14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

EU regulatory information

Information according to Directive

Not subject to 2012/18/EU (SEVESO III)

2012/18/EU (SEVESO III):

National regulatory information

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 4,5,6,10,11,12,14.



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Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

EC/EEC: European Community/European Economic Community

EU: European Union

CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate LC50: Lethal concentration, 50%

LD50: Lethal dose, 50% LL50: Lethal loading, 50% EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic vPvB: very persistent, very bioaccumulative

M-factor: Multiplying factor

ADR: Accord européen sur le transport des marchandises dangereuses par Route

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules MFAG: Medical First Aid Guide

IATA: International Air Transport Association

DGR: Dangerous Goods Regulations

ICAO: International Civil Aviation Organization

TI: Technical Instructions

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.