

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Pharmakaolin B 860

Version	Revision Date:	SDS Number:	Date of last issue: 13.12.2022
1.1	29.03.2023	100000000310	Date of first issue: 13.12.2022

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

1.1 Product identifier

Trade name : Pharmakaolin B 860

REACH Registration Number : Exempted from REACH Registration in accordance with Annex V.7.

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

Use of the Substance/Mixture : Main applications - non-exhaustive list: Ceramics (sanitary-ware, floor tiles, wall tiles, roof tiles, tiles; porcelain, tableware, refractories, etc.), Paper and board, Fibreglass, Paint, Plastic & Rubber, Adhesives and Sealant, Building material & Cement, Animal nutrition, Fertilisers & Agricultural products, Cosmetics & Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Company : Quarzwerke GmbH
Kaskadenweg 40
50226 Frechen
Germany

Telephone : +4922341010

E-mail address of person responsible for the SDS : msds@quarzwerke.com

1.4 Emergency telephone number

112

Emergency telephone number (internal):

+49 (0)2234-101-700

Available outside office hours?:

yes

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Depending on the type of handling and use (e.g. grinding, drying), airborne respirable crystalline silica may be generated. Prolonged and/or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. Principal symptoms of silicosis are cough and breathlessness. Occupational exposure to respirable crystalline silica dust should be monitored and controlled. This product should be handled with care to avoid dust generation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
kaolin	1332-58-7 310-194-1		>= 95
Quartz (SiO ₂)	14808-60-7 238-878-4	STOT RE 1; H372 (Lungs)	< 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	: Do not leave the victim unattended.
If inhaled	: If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of eye contact	: Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	: Keep respiratory tract clear.

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Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Avoid dust formation.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust.
Sweep up and shovel.
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.

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Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : General industrial hygiene practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.

Advice on common storage : No materials to be especially mentioned.

Storage class (TRGS 510) : 13

Further information on storage stability : Keep in a dry place.
No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Quartz (SiO ₂)	14808-60-7	TWA (Respirable dust)	0,1 mg/m ³	2004/37/EC
Further information: Carcinogens or mutagens				
		TWA (Alveolar dust fraction)	0,05 mg/m ³ (Silica)	TRGS 559 - Quarzhaltiger Staub (Dust containing quartz)
Further information: Assessment standard related to a shift of 8 hours. The maximum exceedance factor is 8.				

8.2 Exposure controls

Engineering measures

Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

Personal protective equipment

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Eye/face protection	:	Safety glasses
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Respiratory protection	:	Equipment should conform to EN 143 Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	solid, powder
Colour	:	white
Odour	:	odourless
Odour Threshold	:	Not applicable
Melting point/freezing point	:	> 1.700 °C
Flammability	:	The product is not flammable.
Flash point	:	Not applicable
pH	:	5 - 8
Solubility(ies) Water solubility	:	negligible
Vapour pressure	:	Not applicable
Density	:	2,5 - 2,7 g/cm3
Particle characteristics Assessment	:	Commission Regulation (EU) 2020/878 Assessment: This substance/ mixture does not contain nanoforms
Shape	:	Shape: Tabular - Platy

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

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10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.

10.4 Conditions to avoid

Conditions to avoid : Not applicable

10.5 Incompatible materials

Materials to avoid : Not applicable

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

Quartz (SiO₂):

Carcinogenicity - Assessment : Lung cancer excess risk is demonstrated only under high occupational exposures to Respirable Crystalline Silica. The lung cancer excess risk is restricted to subjects who contracted silicosis.

Reproductive toxicity

Not classified based on available information.

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STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Quartz (SiO₂):

Exposure routes	:	Inhalation
Target Organs	:	Lungs
Assessment	:	Causes damage to organs through prolonged or repeated exposure.
Remarks	:	Prolonged and/or massive exposure to respirable crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica. So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see section 16 below).

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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Further information

Product:

Remarks	:	No data available
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SECTION 12: Ecological information

12.1 Toxicity

Components:

Quartz (SiO₂):

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
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Chronic aquatic toxicity : This product has no known ecotoxicological effects.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Product:

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good

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IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

Water hazard class (Germany) : nwg not water endangering
Code Number: 765
Classification according to AwSV, Annex 1 (4)

TA Luft List (Germany) : 5.2.1 Total dust:
Applicable
5.2.2 Inorganic substances in powdered form:
Not applicable
5.2.4 Inorganic substances in gaseous form:
Not applicable
5.2.5 Organic Substances:
Not applicable
5.2.7.1.1 Carcinogenic substance:
Not applicable
5.2.7.1.1 Quartz fine dust PM4:
Applicable
5.2.7.1.1 Formaldehyde:
Not applicable
5.2.7.2 Poorly degradable, easily enrichable and highly toxic organic substances:
Not applicable
5.2.7.1.3 Substances toxic to reproduction:
Not applicable
5.2.7.2 Poorly degradable, easily enrichable and highly toxic organic substances:
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

Other regulations:

TRGS 906 - Verzeichnis krebserzeugender Tätigkeiten oder Verfahren nach § 3 Abs. 2 Nr. 3

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TRGS 900 - Arbeitsplatzgrenzwerte (Occupational exposure limit values)

TRGS 559 - Quarzhaltiger Staub (Dust containing quartz)

TRGS 500 - Schutzmaßnahmen (Protective measures)

TRGS 402 - Ermitteln und Beurteilen der Gefährdungen bei Tätigkeiten mit Gefahrstoffen: Inhalative Exposition

The components of this product are reported in the following inventories:

TCSI	: On the inventory, or in compliance with the inventory
TSCA	: All substances listed as active on the TSCA inventory
AIIC	: On the inventory, or in compliance with the inventory
DSL	: All components of this product are on the Canadian DSL
ENCS	: On the inventory, or in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: On the inventory, or in compliance with the inventory
PICCS	: On the inventory, or in compliance with the inventory
IECSC	: On the inventory, or in compliance with the inventory
NZIoC	: On the inventory, or in compliance with the inventory
EINECS / CH	: The formulation contains substances listed on the Swiss Inventory, On the inventory, or in compliance with the inventory
REACH	: On the inventory, or in compliance with the inventory
TECI	: On the inventory, or in compliance with the inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

Full text of H-Statements

H372 : Causes damage to organs through prolonged or repeated exposure if inhaled.

Full text of other abbreviations

STOT RE	: Specific target organ toxicity - repeated exposure
2004/37/EC	: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
2004/37/EC / TWA	: Long term exposure limit

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Training advice : Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations.

Other information : In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.)
In 2009, in the Monographs 100 series, IARC confirmed its classification of Silica Dust, Crystalline, in the form of Quartz and Cristobalite (IARC Monographs, Volume 100C, 2012).
In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silico-

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sis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003). A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25 April 2006. This autonomous agreement, which receives the European Commission's financial support, is based on a Good Practices Guide. The requirements of the Agreement came into force on 25 October 2006. The Agreement was published in the Official Journal of the European Union (2006/C 279/02). The text of the Agreement and its annexes, including the Good Practices Guide, are available from <http://www.nepsi.eu> and provide useful information and guidance for the handling of products containing respirable crystalline silica. Literature references are available on request from EUROSIL, the European Association of Industrial Silica Producers.

Works involving exposure to respirable crystalline silica dust generated by a work process are included in Directive (EU) 2017/2398 of 12 December 2017 amending Directive 2004/37/EC on the Protection of Workers from the risks related to exposure to Carcinogens or Mutagens at work.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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