

Safety Data Sheet

according to regulation (EC) No. 1907/2006 (REACH)

Rev. 2014-10

1. Identification of the substance/preparation and of the company/undertaking

Information on the product

Trade name: picodent easysoft

Company/undertaking identification:

picodent GmbH
Lüdenscheider Str. 24-26
D-51688 Wipperfürth

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Responsible Department:

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picodent GmbH, Wipperfürth

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2. Hazards identification

GHS/CLP (EC Regulation 1272/2008) Classification:

Physical:
Health:
Environmental

Not Classified
Specific Target Organ Toxicity (Repeated Exposure) Category 1
Not Classified

GHS/CLP (EC Regulation 1272/2008) Label:



Statements of Hazard

DANGER
H372 Causes damage to lungs through prolonged or repeated exposure by inhalation

Prevention

P260 - Do not breathe dust.
P264 – Wash thoroughly after handling.
P270 – Do not eat, drink or smoke when using this product.
P314 – Get medical advice/attention if you feel unwell.
P501 - Dispose of contents/containers in accordance with local regulations.

EU Preparation Classification (1999/45/EC):

Harmful (Xn) R48/20

Other Label Information:

Prolonged overexposure to respirable crystalline silica may cause lung disease (silicosis) and increase the risk of lung cancer. Risk of cancer depends on duration and level of exposure. When mixed with water in a container, this material hardens and generates some heat, may warm container's exterior sides.

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3. Composition/information on ingredients

Ingredient	CAS No./EINECS No.	Percent	EC 1272/2008 (CLP)	EC Substance Classification
Crystalline Silica Quartz	14808-60-7/238-878-4	Less than 50%	STOT RE1 H372	Xn R48/20
Crystalline Silica Cristobalite	14464-46-1/238-455-4	Greater than 30%	STOT RE 1 H372	Xn R48/20
Calcium Sulfate Hemihydrate	26499-65-0 / 231-900-3	Less than 40%	Not Applicable	Not Applicable

See Section 16 for further information on EU Classification.

4. First aid measures

Eye Contact:	Flush eyes with large quantities of water for 15 minutes, holding the eyelids apart. Get medical attention if irritation develops and persists.
Skin Contact:	No first aid is generally required. Wash skin with soap and water after use.
Ingestion:	May cause gastrointestinal discomfort and intestinal blockage. If swallowed, drink 1 or 2 glasses of water to dilute. Never give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.
Inhalation:	Remove victim to fresh air. If irritation or other symptoms persist, get medical attention.

5. Fire-fighting measures

Extinguishing Media:	Use media appropriate to the surrounding fire.
Firefighting Procedures:	Firefighters should wear full emergency equipment and NIOSH approved positive pressure self-contained breathing apparatus in fires involving chemicals.
Unusual Fire/Explosion Hazards:	None known
Known or Anticipated Hazardous Products of Combustion:	Thermal decomposition (above 1450°C) may generate SOx gases and leave calcium oxide solids behind.

6. Accidental release measures

Accidental Release Measures:	Wear appropriate protective clothing as described in Section 8. Collect using dustless method (HEPA vacuum or wet method) and place in appropriate container for use. Do not use compressed air. Report releases as required by local, state and federal authorities.
Personal Precautions:	Avoid contact with eyes and skin. Do not breathe dust.
Environmental Precautions:	None known.

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7. Handling and storage

Handling:	Avoid contact with the eyes and skin. Do not breathe dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation and proper dust collection methods to keep exposure level below occupational exposure limits. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.
Storage:	Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage.

8. Exposure controls/personal protection

Occupational Exposure Limits:	
Crystalline Silica, Quartz:	10 mg/m ³ TWA PEL (respirable fraction) % Silica + 2 0.025 mg/m ³ TWA TLV (respirable fraction) 0.3 mg/m ³ TWA UK WEL 0.15 mg/m ³ TWA MAK
Crystalline Silica, Cristobalite:	0.025 mg/m ³ TWA ACGIH TLV (respirable fraction) 10 mg/m ³ TWA PEL (respirable fraction) 2(% Silica + 2)
Calcium Sulfate Hemihydrate:	15 mg/m ³ TWA OSHA PEL (total dust) 5 mg/m ³ TWA OSHA PEL (respirable fraction)
Engineering Controls:	Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits.
Personal Protective Equipment:	
Eye Protection:	Safety glasses or goggles if needed to avoid eye contact
Skin Protection:	Wear rubber or other impervious gloves to avoid prolonged or repeated contact.
Respiratory Protection:	If the exposure limits are exceeded, an approved particulate respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.
Other Protective Clothing or Equipment:	Impervious clothing as needed to avoid contamination of personal clothing.

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9. Physical and chemical properties

Appearance and Odor:	White or tan White colored free flowing powder sand with little to no odor.
Boiling Point:	Not available
Melting Point:	Not available
Freezing Point:	Not available
Specific Gravity:	2.50
Solubility in Water:	1.5%
pH:	6-8
Vapor Pressure (mmHg):	Not available
Vapor Density:	Not applicable
Evaporation Rate:	None
Viscosity:	Not applicable
% Volatile by Volume:	Not available
Flashpoint:	Not flammable
Flammable Limits in Air:	LEL: Not applicable UEL: Not applicable
Autoignition Temperature:	Not applicable

10. Stability and reactivity

Stability:	Stable
Conditions to Avoid:	Contact with water or high humidity.
Incompatibility with Other Materials:	Avoid oxidizing agents and acids.
Hazardous Decomposition Products:	Crystalline silica will dissolve in hydrofluoric acid and produce silicone tetrafluoride. Reaction with water or acids generates heat. Thermal decomposition (above 1450°C) may generate calcium oxide and sulfur dioxide.
Hazardous Polymerization:	Will not occur.

11. Toxicological information

Potential Health Effects	
Eyes:	Contact may cause mechanical irritation and possible injury.
Skin:	May cause irritation. When mixed with water in a container, this material hardens and generates some heat, may warm container's exterior sides.
Ingestion:	No adverse effects expected for normal, incidental ingestion. Large amounts may cause gastrointestinal irritation and blockage.
Inhalation:	Inhalation of dust may cause irritation to the nose, throat and upper respiratory tract with coughing and shortness of breath.
Chronic Health Effects:	Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling and sometimes fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness and reduced pulmonary function. Prolonged or repeated skin contact may cause dermatitis.
Carcinogenicity:	Crystalline silica quartz and cristobalite are listed as "Carcinogenic to Humans" (Group 1) by IARC and "Known to be a Human Carcinogen" by NTP.

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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 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 silicosis (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).

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).

Medical Conditions Aggravated by Exposure: Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:	Crystalline Silica (as Quartz)	Oral Rat LD50 - >22,500 mg/kg.
	Crystalline Silica (as Cristobalite)	No data available
	Calcium Sulfate Hemihydrate	Oral Rat LD50:>5000 mg/kg

12. Ecological information

Crystalline Silica (as Quartz)	72 hr LC50 carp: >10,000 mg/L
Crystalline Silica (as Cristobalite)	No data available
Calcium Sulfate Hemihydrate	No data available

13. Disposal considerations

Dispose in accordance with federal, state, and local regulations.

14. Transport information

DOT Shipping Name:	Not Regulated
DOT Hazard Class:	N/A
UN Number:	N/A
DOT Labels Required (49CFR172.101):	N/A
IATA Shipping Name:	Not Regulated
IATA Hazard Class:	N/A
UN Number:	N/A
IATA Hazard Labels Required:	N/A
IMDG Shipping Name:	Not Regulated
IMDG Class:	N/A
UN Number:	N/A
IMDG Label:	N/A

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15. Regulatory information

U.S. FEDERAL REGULATIONS:

CERCLA 103 Reportable Quantity:

This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA TITLE III:

Hazard Category For Section 311/312: Chronic health

Section 313 Toxic Chemicals:

This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ):

None

EPA Toxic Substances Control Act (TSCA) Status:

All of the components of this product are listed on the TSCA inventory.

U.S. STATE REGULATIONS

California Proposition 65:

This product contains the following substances known to the State of California to cause cancer: Crystalline Silica as Quartz: less than 50%, Crystalline Silica as Cristobalite: greater than 30%.

INTERNATIONAL REGULATIONS:

Canadian Environmental Protection Act:

All of the components in this product are listed on the Domestic Substances List (DSL). Canadian WHMIS Classification: Class D Division 2A (Very toxic material causing other toxic effects)

European Community Labeling (1999/45/EC):



Contains Crystalline Silica (Quartz and Cristobalite)
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
S22 Do not breathe dust.
S38 In case of insufficient ventilation, wear suitable respiratory equipment.

European Inventory of New and Existing Chemicals Substances (EINECS):

All of the components in this product are listed on the EINECS inventory.

Australian Inventory of Chemical Substances:

All of the components in this product are listed on the AICS for Australia.

China Inventory of Existing Chemicals and Chemical Substances:

All of the components in this product are listed on the IECSC for China.

Japanese Existing and New Chemical Substances:

All of the components in this product are listed on the Japanese ENCS list.

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Korean Existing Chemicals List:

All of the components in this product are listed on the KECL for Korea.

Philippine Inventory of Chemicals and Chemical Substances:

All of the components in this product are listed on the PICCS.

16. Other information

HMIS Hazard Rating:

Health – 0* Fire Hazard – 0 Reactivity – 0
*Chronic Health Hazard

**EU Classes and Risk Phrases for Reference
(See Sections 2 and 3):**

Xn Harmful
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.
STOT RE 1: Specific Target Organ Toxicity, Repeated Exposure 1
H372: Causes damage to lungs through prolonged or repeated exposure via inhalation

Training

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.

Social Dialogue on Respirable Crystalline Silica

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.