

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 07.03.2023

Version number 5

Revision: 07.03.2023

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

1.1 Product identifier

Trade name **Kera Vest, Kera Vest 3D**

Article number: 1001014, 1001014-3D

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

No further relevant information available.

Application of the substance / the mixture

Dental impression material

Auxiliary for dental technology

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Eisenbacher Dentalwaren ED GmbH

Dr. - Konrad - Wiegand - Straße 9

63939 Wörth / Main, Germany

Tel.: 0049 9372 / 94 04 - 0

www.eisenbacher.de

Information:

product management tel.: +49 93 72 - 94 04 - 0

or by mail: info@eisenbacher.de

1.4 Emergency telephone number:

Tel.: +49 (0) 9372 9404 0, Monday to Friday 8.00 a.m. to 5.00 p.m., in German and English, also contact the local poison control centres

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

STOT RE 2 H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms



GHS08

Signal word Warning

Hazard-determining components of labelling:

Quartz (SiO₂)

cristobalite

Hazard statements

H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Precautionary statements

P260 Do not breathe dust.

P284 In case of inadequate ventilation wear respiratory protection.

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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Information pertaining to particular dangers for man and environment

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Contains quartz. Do not inhale dust.

May cause lung injury (Silicosis/lung cancer)

Contains cristobalite. Do not inhale dust.

May cause lung injury (Silicosis/lung cancer)

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Blend of quartz and cristobalite powder, ammonium phosphate and magnesium oxide

Dangerous components:

CAS: 14808-60-7 Quartz (SiO₂) 50-100%

EINECS: 238-878-4 STOT RE 2, H373

CAS: 14464-46-1 cristobalite 10-<25%

EINECS: 238-455-4 STOT RE 2, H373

CAS: 14808-60-7 Quartz (SiO₂) 2.5-<10%

EINECS: 238-878-4 STOT RE 1, H372

CAS: 1309-48-4 magnesium oxide 2.5-<10%

EINECS: 215-171-9 substance with a Community workplace exposure limit

Additional information

This product contains more than 10% quartz / cristobalite (fine fraction, alveolar), which is classified as STOT RE1.

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation : Supply fresh air; consult doctor in case of symptoms.

After skin contact :

Instantly rinse with water.

The product is not skin irritating.

After eye contact : Rinse opened eye for 15 minutes under running water.

After swallowing : In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

Use fire fighting measures that suit the environment.

CO₂, extinguishing powder or water jet. Fight larger fires with foam.

5.2 Special hazards arising from the substance or mixture

Fire can cause release of :

Ammonia (NH₃)

5.3 Advice for firefighters

Protective equipment:

Wear self-contained breathing apparatus.

Do not inhale explosion gases or combustion gases.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Avoid causing dust.
- Use breathing protection against the effects of fumes/dust/aerosol.
- Wear protective clothing.

6.2 Environmental precautions: No special measures required.

6.3 Methods and material for containment and cleaning up:

- Collect mechanically.
- Dispose of contaminated material as waste according to section 13.

6.4 Reference to other sections

- See section 7 for information on safe handling
- See section 8 for information on personal protection equipment.
- See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Prevent formation of dust.
- Provide suction extractors if dust is formed.
- Ensure that suitable extractors are available on processing machines
- Wear breathing protection when decanting larger quantities without extractor facilities.
- Use appropriate industrial vacuum cleaners or central vacuum systems for dust removal.

Information about protection against explosions and fires:

- The product is not flammable
- No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage

- Requirements to be met by storerooms and containers:** No special requirements.
- Information about storage in one common storage facility:** Not required.
- Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.
- 7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

14808-60-7 Quartz (SiO₂)

BOELV (European Union) Long-term value: 0.1* mg/m³
*respirable fraction

14808-60-7 Quartz (SiO₂)

BOELV (European Union) Long-term value: 0.1* mg/m³
*respirable fraction

1309-48-4 magnesium oxide

WEL (Great Britain) Long-term value: 10* 4** mg/m³
(as Mg) *inhalable dust **fume and respirable dust

Additional information:

- The lists that were valid during compilation were used as a basis.
- The general dust limit value of 1.25 mg / m³ (alveolar fraction) and 10 mg / m³ (respirable fraction) must be observed (TRGS 900, 2015).

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8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures

Vacuum clean contaminated clothing. Do not blow or brush off contamination.
The usual precautionary measures should be adhered to in handling the chemicals.
Keep away from foodstuffs, beverages and food.
Wash hands during breaks and at the end of the work.
Store protective clothing separately.

Breathing equipment:

Short term filter device: ABEK-filter
Filter P2.

In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.

Protection of hands:

Protective gloves:

In case of spray contact at least protection index 2 recommended, according to more than 30 min. penetration time (EN 374).

Layer thickness of gloves at least: 0.4 mm

In case of prolonged and intensive contact protection index 6 recommended, according to more than 480 min. penetration time (EN 374).

Layer thickness of gloves at least: 0.7 mm

Material of gloves

Butyl rubber, BR
Fluorocarbon rubber (Viton)
Nitrile rubber, NBR
Natural rubber, NR
Chloroprene rubber, CR
Neoprene gloves

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Tightly sealed safety glasses (DIN 58211, EN 166)

Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Solid

Colour: Whitish

Smell: Odourless

Odour threshold: not applicable

pH-value at 20 °C: 6 (Suspension)

Change in condition

Melting point/freezing point: >1,400 °C

Initial boiling point and boiling range: not applicable

Flash point: Not applicable

Inflammability (solid, gaseous) not applicable

Ignition temperature: not applicable

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. Decomposition temperature:	not determined
. Explosive properties:	Product is not explosive.
. Critical values for explosion:	
Lower:	not applicable
Upper:	not applicable
. Dust explosion class:	
Oxidising properties	not applicable
. Steam pressure:	Not applicable. not applicable
. Density at 20 °C	1.15 g/cm ³
. Evaporation rate	not applicable
. Solubility in / Miscibility with Water:	Unsoluble
. Partition coefficient: n-octanol/water:	not determined
. Viscosity:	
dynamic:	Not applicable. not applicable
kinematic:	Not applicable. not applicable
. Solvent content:	
Water:	0.0 %
Solids content:	100.0 %
. 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- . **10.1 Reactivity**
No further relevant information available.
No further relevant information available.
- . **10.2 Chemical stability**
- . **Thermal decomposition / conditions to be avoided:** none
- . **10.3 Possibility of hazardous reactions** No dangerous reactions known
- . **10.4 Conditions to avoid** No further relevant information available.
- . **10.5 Incompatible materials:** void
- . **10.6 Hazardous decomposition products:** At preheating temperature (250-300°C) slight odour like ammonia.

* SECTION 11: Toxicological information

- . **11.1 Information on toxicological effects**
- . **Acute toxicity** Based on available data, the classification criteria are not met.
- . **LD/LC50 values that are relevant for classification:**
- 7722-76-1 ammonium dihydrogenorthophosphate**
- Oral LD50 >2,001 mg/kg (rat)
- Dermal LD50 >5,001 mg/kg (rat)

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- . **Primary irritant effect:**
- . **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- . **Serious eye damage/irritation** Moderate irritation
- . **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- . **Subacute to chronic toxicity:**
 - Do not breathe dust.
 - Harmful: possible risk of irreversible effects through inhalation.
- . **Additional toxicological information:**
- . **Repeated dose toxicity**
 - May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- . **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)** No further relevant information available.
- . **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- . **Carcinogenicity** Based on available data, the classification criteria are not met.
- . **Reproductive toxicity** Based on available data, the classification criteria are not met.
- . **STOT-single exposure** Based on available data, the classification criteria are not met.
- . **STOT-repeated exposure**
 - May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- . **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- . **12.1 Toxicity**
- . **Aquatic toxicity:**
 - 7722-76-1 ammonium dihydrogenorthophosphate**
 - LC50 (96 h) (static) >100 mg/L (rainbow trout)
 - NOEC (static) 85.9 mg/L (rainbow trout)
- . **12.2 Persistence and degradability** No further relevant information available.
- . **Other information:**
 - Inorganic salts are basically not biodegradable.
 - Easy elimination possible by flocculation or adsorption by sludge.
- . **12.3 Bioaccumulative potential** No further relevant information available.
- . **12.4 Mobility in soil** No further relevant information available.
- . **Ecotoxicological effects:**
- . **Other information:**
 - No AOX
 - No VOC (0%) according to EC-directive 1999/13/EC
- . **Additional ecological information:**
- . **General notes:**
 - Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- . **12.5 Results of PBT and vPvB assessment**
- . **PBT:** Not applicable.
- . **vPvB:** Not applicable.
- . **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- . **13.1 Waste treatment methods**
- . **Recommendation**
 - Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
 - Must be specially treated in adherence to official regulations.

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- . **Uncleaned packaging:**
- . **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Empty contaminated packagings thoroughly. They can be recycled after thorough and proper cleaning.
Packagings that cannot be cleaned are to be disposed of in the same manner as the product.
- . **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- | | |
|--|---|
| . 14.1 UN-Number | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.2 UN proper shipping name | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.3 Transport hazard class(es) | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . Class | Void |
| . 14.4 Packing group | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.5 Environmental hazards: | Not applicable. |
| . 14.6 Special precautions for user | Not applicable. |
| . 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| . Transport/Additional information: | Not dangerous according to the above regulations. |
| . UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- . **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- . **Directive 2012/18/EU**
- . **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- . **National regulations**
- . **Information about limitation of use:** Employment restrictions concerning young persons must be observed.
- . **Other regulations, limitations and prohibitive regulations**
The general dust exposure limit of 1.25 mg/m³, measured as alveolic part has to be observed (German TRGS 900, 2015).
TRGS 559 - Mineral dust
- . **Chemical inventories:**
All ingredients listed in:
Europe (EINECS): yes
Australia (AICS): yes
Canada (DSL): yes
Japan (ENCS): yes
China (IECSC): yes
Korea (KECI): yes
USA (TSCA): yes
Philippines (PICCS): yes
- . **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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* SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

. **Relevant phrases**

H372 Causes damage to organs through prolonged or repeated exposure.

H373 May cause damage to organs through prolonged or repeated exposure.

. **Contact:** info@eisenbacher.de

. **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

. **Sources:** source ECHA: European Chemicals Agency, <http://echa.europa.eu/>

. * **Data compared to the previous version altered.**