Safety Data Sheet

according to regulation (EU) No. 1907/2006

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

1.1 Information on the product Phoshate-bound investment material

Trade name: picovest royal

1.2 Relevant identified uses of the substance/preparation and uses that are inadvisable No further relevant information available

Application of the substance / the preparation Dental investment material (Auxiliary for dental technology)

1.3 Details about the supplier of the safety data sheet

Manufacturer/Supplier:

Company name: picodent GmbH
Street: Lüdenscheider Str. 24-26
City: D-51688 Wipperfürth
Telephone: +49 2267 6580-0
E-Mail: picodent@picodent.de
Internet: www.picodent.de
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1.4 Emergency contact number: Telephone-No. +49 2267 6580-0
(07.30 am - 4.45 pm) Telephone-No. +49 171 6126850

2. Hazards identification

Categorisation of the substance/preparation
Categorisation under Regulation (EC) 1272/2008 [CLP]. Specific target organ toxicity (repeat exposure) (inhalation, lungs) Category 1 H372

2.2. Labelling elements Labelling in line with
EC Directive (EC) 1272/2008
Hazardous component(s) (GHS) Quartz (SiO2)
Cristobalite

Symbol(s)

Signal word **Danger**
Danger note H372 – Causes damage to lungs through prolonged or repeated exposure.

Safety note

P260 – Do not breathe dust.
P264 – Wash hands 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/container in accordance with local waste disposal regulations.

2.3. Other hazards

May cause silicosis.
Ammonia is released when heated to over 200 °C. Ammonia is a respiratory irritant. No PBT/vPvB assessment is available because a chemical safety assessment is not required/was not conducted.

3. Composition/information on ingredients

Information about components / Dangerous ingredients according to the EU CLP Regulation (EC) no. 1272/2008

-Quartz (SiO2)			50%–70%		
CAS no.	14808-60-7	EC no.	238-878-4		
Specific target organ toxicity (repeat exposure) (inhalation, lungs)				Category 1	H372
Cristobalite			10%–30%		
CAS no.	14464-46-1	EC no.	238-455-4		
Specific target organ toxicity (repeat exposure) (inhalation, lungs)				Category 1	H372
-Magnesium oxide			5%–15%		
CAS no.	1309-48-4	EC no.	215-171-9		
-Ammonium dihydrogen phosphate			5%–15%		
CAS no.	7722-76-1	EC no.	231-764-5		

Information about components / Dangerous ingredients according to Directive 67/548/EC and Directive 1999/45/EC

-Quartz (SiO2)			50%–70%
CAS no.	14808-60-7	EC no.	238-878-4
Xn R48/20			
Cristobalite			10%–30%
CAS no.	14464-46-1	EC no.	238-455-4
Xn R48/20			
-Magnesium oxide			5%–15%
CAS no.	1309-48-4	EC no.	215-171-9
-Ammonium dihydrogen phosphate			5%–15%
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For texts of H-phrases, see Chapter 16.
For texts of R-phrases, see Chapter 16.

4. First aid measures

4.1. Description of first aid measures

Inhalation

If vapours/smoke forms (ammonia): Bring affected person into the fresh air.

If particulate matter is released: Bring affected person into the fresh air.

Potential symptoms: Localised contact is likely to cause irritation and potentially corrosivity to the mucous membranes (eyes, respiratory system).
Seek medical advice in the event of symptoms.

Skin contact Wash with soap and water.

Eye contact If ammonia vapour gets in the eyes

In the event of symptoms: Hold the eye open and rinse with plenty of clean water.
Consult an ophthalmologist.

If particulate matter is released: Possible symptoms caused by foreign body effect.
Hold the eye open and rinse with plenty of clean water.
f eye irritation persists, consult an ophthalmologist.

Swallowing No specific first aid measures required.

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

Symptoms No known

Risks No known

4.3. Indication of any immediate medical attention or special treatment needed Treat symptomatically.

5. Fire-fighting measures

5.1. Extinguishants

Suitable extinguishants: All extinguishants are suitable.

5.2. Special hazards arising from the substance or mixture Ammonia is released when heated to over 200 °C.
The product itself is non-combustible.

5.3. Notes on fire extinguishing

Suitable extinguishants: Fire extinguishing measures must be adapted to the place of use.
Use standard protective equipment for firefighting.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency measures If particulate matter is released:
Always wear breathing apparatus.

6.2. Environmental precautions Prevent the product from draining into the soil, bodies of water or sewage system.

6.3. Methods and material for containment and cleaning up Clean up mechanically.

6.4. Reference to other sections Wear personal protective equipment; see section 8.
For notes on disposal, see section 13.

7. Handling and storage

7.1. Protective measures for safe handling

If particulate matter is released: Always wear breathing apparatus.

If vapours are released: Always wear breathing apparatus. Use an extractor system if necessary. You must adhere to the standard precautions for handling chemicals.

7.2. Conditions for safe storage, including incompatibilities

Requirements of storage rooms and containers Storage

Store in a cool, dry place.
Keep containers tightly closed.
Processed opened containers immediately.

Storage class (LGK) 13 - Non-flammable solids

7.3. Specific end applications

No specific end applications beyond the scope of those mentioned in Section 1 are currently known.

8. Exposure controls/personal protection

8.1. Parameters to be monitored

-Quartz (SiO2)			
CAS no.	14808-60-7	EC no.	238-878-4
Parameters to be monitored			(DFG MAK)
Type of exposure	Alveolar fraction		
	Included in the regulation, but with no accompanying data. See regulation for more details.		
Cristobalite			
CAS no.	14464-46-1	EC no.	238-455-4
Parameters to be monitored			(DFG MAK)
Type of exposure	Alveolar fraction		
	Included in the regulation, but with no accompanying data. See regulation for more details.		
-Magnesium oxide			
CAS no.	1309-48-4	EC no.	215-171-9
Parameters to be monitored	1.5 mg/m³		MAK (DFG MAK)
Type of exposure	Alveolar fraction		
	Listed		
Parameters to be monitored	4 mg/m3		MAK (DFG MAK)
Type of exposure	Inhalable fraction		
	Listed		
Parameters to be monitored			MAK (DFG MAK)
Type of exposure	Smoke		
	No MAK [maximum occupational exposure limit] value determined.		
Parameters to be monitored	10 mg/m³		AGW:(TRGS 900)
Short-term value	2		
Type of exposure	Inhalable fraction		
Parameters to be monitored	1.25 mg/m³		AGW:(TRGS 900)
Type of exposure	Alveolar fraction		

8.2. Limitation and monitoring of exposure

Technical protective measures	Ensure sufficient extraction/ventilation at the workstation. Avoid dust accumulation. For personal protective equipment
Mask	A suitable mask must be worn in the event that workplace limit values are exceeded and/or large quantities of the substance are released (leaks, spills, dust). If the workplace limit values are exceeded, wear a half mask with P3 particle filter.
Gloves	No specific measures required.
Eye protection	Wear safety glasses with side guards. If dust is released, wear goggles.
Protecting the skin and body	Suitable protective clothing recommended, avoid contaminating the clothing with the product. Change out of contaminated clothing. Wash contaminated clothing after wear.
Hygiene measures	Apply standard precautions for handling chemicals. Do not eat, drink or smoke during use. Wash hands and/or face before taking a break or finishing work.

9. Physical and chemical properties

9.1. Details about fundamental physical and chemical properties

Appearance	
Form	Powder
Colour	Depends on colourings added
Smell	Almost odourless
pH	Approx. 5
Melting point/melting range	> 1,500 °C
Flash point	Non-flammable
Water solubility:	Poor solubility
Autoflammability	Not autoflammable, not self-heating.

9.2. Other information

Bulk density	1,100–1,200 kg/m3
Other information:	No other physical or chemical information has been determined.

10. Stability and reactivity

10.1. Reactivity No data available

10.2. Chemical stability The product is chemically stable.

10.3. Possible dangerous reactions

Possible dangerous Reactions	May decompose in heat. Ammonia is released when heated to over 200 °C.

10.4. Conditions to avoid If used correctly, there are no dangerous reactions known.

10.5. Incompatible materials Moisture, water

10.6. Hazardous decomposition products Ammonia

11. Toxicological information

11.1. Information about toxicological effects

No in vivo experiments have been conducted for this product.

Acute toxicity upon oral ingestion	No data available
Acute toxicity upon inhalation	No data available
Acute toxicity upon absorption by the skin	No data available
Skin irritation	No data available
Eye irritation	No data available
Sensitisation	No data available
Toxicity upon repeated absorption	No data available
Repeat STOT evaluation	Exposure routes: Inhalation Target organs: Lungs Not subject to labelling in accordance with the GHS Regulation, categorisation and labelling of the preparation due to voluntary self-classification of respirable crystalline silica (RCS) by the Industrial Minerals Association Europe (IMA Europe).
Mutagenicity assessment	No data available
Carcinogenicity	No data available
Toxicity to reproduction	No data available
Testing in humans	May cause mechanical irritation of the skin and mucous membranes and respiratory system. Ammonia vapour: Localised contact is likely to cause irritation and potentially corrosivity to the skin and mucous membranes (eyes, respiratory system; also in the digestive system after swallowing).
Further details:	If handled and stored correctly, no hazardous reactions are known to occur. In the event of improper use, product may cause silicosis.

12. Ecological information

12.1. Toxicity No ecotoxicological studies have been conducted for this product.

12.2. Persistence and degradability

Biodegradability No data available

12.3. Bioaccumulation potential

Bioaccumulation No data available

12.4. Mobility in the soil

Mobility No data available

12.5. Results of the PBT and vPvB assessment No PBT/vPvB assessment is available because a chemical safety assessment is not required/was not conducted.

12.6. Other detrimental effects
Further information Do not allow to enter the sewage system or soil.

13. Disposal considerations

13.1. Waste treatment practices
Product Disposal in accordance with official local regulations.
Contaminated packaging Disposal in accordance with official local regulations.

14. Transport information

Not classed as hazardous goods according to transport regulations.

14.1. UN numbers: --

14.2. Proper UN shipping name: --

14.3. Transport hazard category: --

14.4. Packaging group: --

14.5. Environmental hazards: --

14.6. Special precautions for the user: No

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific to the substance or preparation
National regulations
Water hazard class WGK 1, slightly hazardous to water
Categorisation according to VwVwS, appendix 4
Occupational safety regulations: TRGS 906 must be applied

15.2. Chemical safety assessment
Chemical safety assessment According to Items 2(8), 2(9) and Item 14 of the REACH regulation, a chemical safety assessment is not required.

16. Other information

Texts for the R-phrases
Quartz (SiO2)
R48/20 Harmful: Danger of serious damage to health by prolonged exposure through inhalation.
Cristobalite
R48/20 Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Texts for the H-phrases
Quartz (SiO2) H372 – Causes damage to lungs through prolonged or repeated exposure.
Cristobalite H372 – Causes damage to lungs through prolonged or repeated exposure.

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according to regulation (EU) No. 1907/2006

Other information
The information provided here represents our best knowledge and experience to date. However, it implies no liability or other legal responsibility on our part. Subject to modifications due to technological progress or business developments. This information solely describes the nature of our products and services and does not constitute a warranty or guarantee of any kind. The user must have a qualified member of staff carefully check the functionality and potential applications of the products. This also applies to the protection of third party property rights. Reference to the trade names of other companies neither constitutes a recommendation, nor does it imply that similar products could not be used.

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Training
Employees must be informed of the silica content of the product and trained in its proper handling.

Legend

ADR	European Agreement Concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ASTM	American society for materials testing
ATP	Adaptation to technical progress
BCF	Bioconcentration factor
BetrSichV	German Industrial Safety Regulation
c.c.	Closed container
CAS	Chemical Abstracts Service, responsible for assigning CAS numbers
CESIO	European Committee of Organic Surfactants and their Intermediates
ChemG	German Chemicals Act
CMR	Carcinogenic, mutagenic or toxic to reproduction
DIN	Deutsches Institut für Normung e.V. [German Institute for Standardisation]
DMEL	Derived minimum effect level
DNEL	Derived no effect level
EINECS	European Inventory of Existing Commercial Chemical Substances
EC50	Half maximal effective concentration
GefStoffV	German Ordinance on Hazardous Substances
GGVSEB	German Ordinance on the Transport of Dangerous Goods by Road, Rail and Inland Waterways
GGVSee	German Ordinance on the Transport of Dangerous Goods by Sea
GLP	Good laboratory practice
GMO	Genetically modified organism
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
Code ISO	International Organization for Standardization
LOAEL	Lowest dose of a chemical substance where adverse effects were still observed in vivo.
LOEL	Lowest dose of a chemical substance where effects were still observed in vivo.
NOAEL	Highest dose of a substance that does not result in any discernible or measurable adverse effects, including with continuous absorption.
NOEC	No observed effect concentration
NOEL	Dose without any observed effect o.c. Open container
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
PBT	Persistent, bioaccumulating, toxic
PEC	Predicted environmental concentration

PNEC	Predicted concentration for the relevant environment at which damaging environmental effects no longer occur.
REACH	REACH Registration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STOT	Specific target organ toxicity
SVHC	Substance of very high concern
TA	Technical Instructions
TPR	Third-party representation (item 4)
TRGS	German Technical Regulations for Hazardous Substances
VCI	Verband der Chemischen Industrie e.V. [German Chemical Industry Association]
vPvB	Very persistent and very bioaccumulative
VOC	Volatile organic substances
VwVwS	German Regulation on Substances Hazardous to Water
WGK	Water hazard class
WHO	World Health Organization