

Date of issue: 07/15/2025

Version 5

Reviewed on 07/15/2025

## 1 Identification

- **Product identifier**
- **Trade name:** CERABIEN MiLai : Powder Type
- **Article number:** US895-PW
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Dental materials
- **Details of the supplier of the safety data sheet**
- **Contact information :**  
Kuraray America, Inc.  
32 Old Slip, 7th Floor, New York,  
NY 10005 U.S.A.  
Tel: 800-879-1676  
Website: www.kuraraydental.com
- **Emergency telephone number:**  
CHEMTREC; day and night, within USA and Canada  
1-800-424-9300 CCN706984 or +1 703-527-3887 (collect calls accepted)

## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
Carcinogenicity 1A H350 May cause cancer.
- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**  
Cobalt nickel gray periclase (CPMA)  
Quartz (SiO<sub>2</sub>)
- **Hazard statements**  
H350 May cause cancer.
- **Precautionary statements**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Classification according to (d)(1)(ii) of § 1910.1200**  
The SDS issuer does not object to the classifications provided by importers or manufacturers of precursor products.

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# Safety Data Sheet

acc. to OSHA HCS

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- **Hazards not otherwise classified**  
There are no adverse physical or health effects known that are not covered by the hazard classes of the Hazard Communications Standard.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

	Cobalt nickel gray periclase (CPMA)	 Carcinogenicity 1A, H350	0-17%
7631-86-9	Silicon dioxide		0-2%
14808-60-7	Quartz (SiO <sub>2</sub> )	 Carcinogenicity 1B, H350	0-1%

### 4 First-aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** See Section 8.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.  
Ensure adequate ventilation.  
Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.  
Vacuum or sweep material and place in a disposal container. Provide ventilation.  
Use appropriate Personal Protective Equipment (PPE).
- **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 disposal information.

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**7 Handling and storage**

- **Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.  
Avoid contact with skin and eyes, Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors /spray.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store at 1 - 30 °C
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep receptacle tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.  
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

**8 Exposure controls/personal protection**

- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the other constituents have no known exposure limits.

<b>1314-23-4 zirconium dioxide</b>	
PEL	Long-term value: 5 mg/m <sup>3</sup> as Zr
REL	Short-term value: 10 mg/m <sup>3</sup> Long-term value: 5 mg/m <sup>3</sup> as Zr
TLV	Short-term value: 10 mg/m <sup>3</sup> Long-term value: 5 mg/m <sup>3</sup> as Zr; A4
<b>14808-60-7 Quartz (SiO<sub>2</sub>)</b>	
PEL	Long-term value: 0.05* mg/m <sup>3</sup> *resp. dust; 30mg/m <sup>3</sup> /0%SiO <sub>2</sub> +2
REL	Long-term value: 0.05* mg/m <sup>3</sup> *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m <sup>3</sup> *respirable particulate matter, A2

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.
- **Breathing equipment:** Suitable respiratory protective device recommended.

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**Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

**Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**Penetration time of glove material**

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

**Eye protection:**



Tightly sealed goggles

**9 Physical and chemical properties**

**Information on basic physical and chemical properties**

**General Information**

· Physical state	Solid
· Color:	Colored
· Odor:	Odorless
· Odor threshold:	Not determined.
· Melting point/Melting range:	Not determined.
· Boiling point/Boiling range:	Not determined.
· Flammability:	Product is not flammable.
· Explosion limits:	
· Lower:	Not applicable.
· Upper:	Not applicable.
· Flash point:	Not applicable
· Auto ignition temperature:	Not applicable.
· Decomposition temperature:	Not applicable.
· pH-value:	Not determined.
· Kinematic viscosity	Not applicable.
· Solubility in / Miscibility with	
· Water:	Insoluble.
· Partition coefficient (n-octanol/water):	Not applicable.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Relative vapor density	Not applicable.
· Particle characteristics	Not determined.

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- **Other information**
- **Important information on protection of health and environment, and on safety.**
- **Danger of explosion:** Product does not present an explosion hazard.
- **Evaporation rate** Not applicable.

**10 Stability and reactivity**

- **Reactivity** No further relevant information available.
- **Chemical stability** No hazardous reaction when handled and stored according to provisions.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

**11 Toxicological information**

- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **Specific symptoms in biological assay:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** May cause cancer.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - single exposure**  
Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure**  
Based on available data, the classification criteria are not met.
- **Aspiration hazard**  
Based on available data, the classification criteria are not met.  
Based on available data, the classification criteria are not met.
- **Subacute to chronic toxicity:**
- **Interactive effects** No interactive effects between components are known.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

	Cobalt nickel gray periclase (CPMA)	1
14808-60-7	Quartz (SiO <sub>2</sub> )	1

· **NTP (National Toxicology Program)**

	Cobalt nickel gray periclase (CPMA)	K
14808-60-7	Quartz (SiO <sub>2</sub> )	K

- **Alternative sources for toxicological information**  
No non-standard sources for toxicological information where used.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
Carcinogenicity 1A

**12 Ecological information**

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects**
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**13 Disposal considerations**

- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.  
Dispose of this product as medical waste.  
Do not pour product down the drain.  
Dispose of product residues with the packaging.
- **Uncleaned packagings:**
- **Recommendation:**  
Dispose of packaging according to regulations on the disposal of packagings.  
Do not rinse packaging before disposal.  
Non contaminated packagings can be used for recycling.

**14 Transport information**

· <b>UN-Number</b>	
· <b>DOT, IMDG, IATA</b>	Void
· <b>UN proper shipping name</b>	
· <b>DOT, IMDG, IATA</b>	Void
· <b>Transport hazard class(es)</b>	
· <b>DOT, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>Packing group</b>	
· <b>DOT, IMDG, IATA</b>	Void
· <b>Environmental hazards:</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Special precautions for user</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

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<b>· Section 313 (Specific toxic chemical listings):</b>	
	Cobalt nickel gray periclase (CPMA)
	Chrome Tin Pink Sphene
	Zinc iron chromite brown spinel (CPMA)
68186-99-2	Manganese alumina pink corundum (CPMA)
68186-87-8	Cobalt zinc aluminate spinel (CPMA)
	230264 Color stain orange yellow
68186-88-9	Zinc iron chromite brown spinel (CPMA)

· **SARA 311/312:** See Section 2 for the information on physical and health hazards.

<b>· TSCA (Toxic Substances Control Act):</b>		
68186-99-2	Manganese alumina pink corundum (CPMA)	ACTIVE
68186-87-8	Cobalt zinc aluminate spinel (CPMA)	ACTIVE
1314-23-4	zirconium dioxide	ACTIVE
68186-88-9	Zinc iron chromite brown spinel (CPMA)	ACTIVE
7631-86-9	Silicon dioxide	ACTIVE
14808-60-7	Quartz (SiO <sub>2</sub> )	ACTIVE

<b>· Hazardous Air Pollutants</b>	
68186-87-8	Cobalt zinc aluminate spinel (CPMA)

· **Proposition 65**

<b>· Chemicals known to cause cancer:</b>	
	Cobalt nickel gray periclase (CPMA)
7631-86-9	Silicon dioxide
14808-60-7	Quartz (SiO <sub>2</sub> )

<b>· Chemicals known to cause reproductive toxicity for females:</b>	
None of the ingredients is listed.	

<b>· Chemicals known to cause reproductive toxicity for males:</b>	
None of the ingredients is listed.	

<b>· Chemicals known to cause developmental toxicity:</b>	
None of the ingredients is listed.	

· **Carcinogeny categories :**

<b>· EPA (Environmental Protection Agency)</b>	
None of the ingredients is listed.	

<b>· TLV (Threshold Limit Value)</b>		
14808-60-7	Quartz (SiO <sub>2</sub> )	A2

· **Precautionary statements**



**WARNING:** This product can expose you to chemicals including Quartz (SiO<sub>2</sub>), Silicon dioxide and Cobalt nickel gray periclase, which are known to the State of California to cause cancer. For more information, go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

· **National regulations:**

· **Information about limitation of use:**

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

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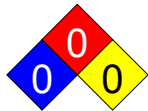
**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.  
Medical devices as defined in the Medical Device Amendments of 1976 are exempt from the provisions of the HCS.

· **Relevant phrases**

H350 May cause cancer.

· **NFPA ratings (scale 0 - 4)**



Health = 0  
Fire = 0  
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = \*0  
Fire = 0  
Reactivity = 0

· **Date of previous version** 04/07/2025

· **Version number of previous version:** 4

· **Date of preparation** 07/15/2025

· **Abbreviations and acronyms:**

- DOT: US Department of Transportation
- ELINCS: European List of Notified Chemical Substances
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Carcinogenicity 1A: Carcinogenicity – Category 1A
- Carcinogenicity 1B: Carcinogenicity – Category 1B

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