

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

- **1.1 Product identifier**
- **Trade name:** CERABIEN MiLai : Powder Type
- **Article number:** 895-PW
- **Registration number** Not applicable
- **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 materials
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier :**
Kuraray Europe GmbH
Philipp-Reis-Str. 4,
65795 Hattersheim am Main
Germany
Phone: +49 (0)69 305 35 835
E-mail: dental.eu@kuraray.com
- **Further information obtainable from:** Supplier
- **1.4 Emergency telephone number:**
[United Kingdom] Only for NHS and other healthcare professionals; UK National Poisons Information Service (NPIS): +44 (0)344 892 0111 Ireland NPIC: +353 (0)1 809 2566
For members of Public; NHS 111 in England: 111, NHS 24 in Scotland: 111, NHS Direct in Wales: 111 or 0845 4647, Ireland NPIC: +353 (0)1 809 2166(8 am to 10 pm)
[3E Company] (Great Britain (London))+44 20 351 47487, (United Kingdom - Domestic)+44 800 680 0425, (United Kingdom - International)+44 808 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray
Access Code: 334674

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:**
This mixture does not contain any substances to be mentioned according to the criteria of Regulation (EC) No 1272/2008.
- **Dangerous components:** Void

SECTION 4: First aid measures

- **4.1 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.

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- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist 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:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** See Section 8.
- **6.2 Environmental precautions:**
Before cleaning, pre-clean the equipment under running water with a damp cloth.
Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Vacuum or sweep material and place in a disposal container. Provide ventilation.
Use appropriate Personal Protective Equipment (PPE).
- **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 disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

Zinc iron chromite brown spinel (CPMA)

WEL (Great Britain) Long-term value: 0.5 mg/m³IOELV (EU) Long-term value: 2 mg/m³
as Cr

1314-23-4 zirconium dioxide

WEL (Great Britain) Short-term value: 10 mg/m³Long-term value: 5 mg/m³
as Zr

60676-86-0 Silica, fused

WEL (Great Britain) Long-term value: 0.08 mg/m³
fused respirable dust

Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Appropriate engineering controls No further data; see section 7.

Personal protective equipment:

Respiratory protection: Suitable respiratory protective device recommended.

Hand protection

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

Eye/face protection Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state

Solid

Colour:

Colored

Odour:

Odourless

Melting point/freezing point:

Not determined.

Boiling point or initial boiling point and boiling range

Not determined.

Flammability

Product is not flammable.

Lower and upper explosion limit

Lower:

Not applicable.

Upper:

Not applicable.

Flash point:

Not applicable

Auto-ignition temperature:

Not applicable.

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| | |
|--|-----------------|
| · Decomposition temperature: | Not applicable. |
| · pH | Not determined. |
| · Kinematic viscosity | Not applicable. |
| · Solubility | |
| · water: | Insoluble. |
| · Partition coefficient n-octanol/water (log value) | Not applicable. |
| · Vapour pressure: | Not applicable. |
| · Density: | Not determined. |
| · Relative vapour density | Not applicable. |
| · Particle characteristics | Not determined. |

· 9.2 Other information

· Information with regard to physical hazard classes

| | |
|--|---|
| · Explosives | Product does not present an explosion hazard. |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

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SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **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** Based on available data, the classification criteria are not met.

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- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

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| · Endocrine disrupting properties |
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| None of the ingredients is listed. |
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SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.

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SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Dispose of this product as medical waste.
Mix residues on disposable materials (e.g. paper, tray) and dispose of them as solid waste.
- **Uncleaned packaging:**
- **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Non contaminated packagings may be recycled.
Do not rinse product containers before disposal.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN number or ID number · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) · ADR, IMDG, IATA · Class | Void |
| · 14.4 Packing group · ADR, ADN, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |

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|---|-----------------|
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

· **Regulated explosives precursors**

None of the ingredients is listed.

· **Regulated poisons**

None of the ingredients is listed.

· **Reportable explosives precursors**

None of the ingredients is listed.

· **Reportable poisons**

None of the ingredients is listed.

- **Directive 94/33/EC:** Care should be taken when people under 18 handle this product.

- **Directive 94/85/EEC:** No further relevant information available.

- **Named dangerous substances - ANNEX I** None of the ingredient is listed.

· **REGULATION (EU) 2019/1021 on persistent organic pollutants (POP)**

None of the ingredients is listed.

· **Regulation (EU) No 649/2012**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **REGULATION (EU) 2024/590 on substances that deplete the ozone layer**

None of the ingredients is listed.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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 Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (GB CLP/GHS) usually if they are in the finished state and intended for the final user.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

· **Classification according to Regulation (EC) No 1272/2008**

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

- **Abbreviations and acronyms:** ELINCS: European List of Notified Chemical Substances

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