

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

- **1.1 Product identifier**
- **Trade name:** CERABIEN ZR : Powder Type
- **Article number:** 824
- **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
- **Labelling of packages where the contents do not exceed 125 ml**
- **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

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**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.
- **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:**  
CO<sub>2</sub>, 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.
- **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.

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· 7.3 Specific end use(s) No further relevant information available.

**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/m<sup>3</sup>IOELV (EU) Long-term value: 2 mg/m<sup>3</sup>  
as Cr**60676-86-0 Silica, fused**WEL (Great Britain) Long-term value: 0.08 mg/m<sup>3</sup>  
fused respirable dust**1314-23-4 zirconium dioxide**WEL (Great Britain) Short-term value: 10 mg/m<sup>3</sup>Long-term value: 5 mg/m<sup>3</sup>  
as Zr**1344-28-1 aluminium oxide**WEL (Great Britain) Long-term value: 10\* 4\*\* mg/m<sup>3</sup>  
\*inhalable dust \*\*respirable dust**18282-10-5 tin dioxide**WEL (Great Britain) Short-term value: 4 mg/m<sup>3</sup>Long-term value: 2 mg/m<sup>3</sup>  
as SnIOELV (EU) Long-term value: 2 mg/m<sup>3</sup>  
as Sn· **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

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**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.           |
| · 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 at 20 °C:                                        | 2.6 g/cm <sup>3</sup>     |
| · 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                                          |

**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.

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

- **Endocrine disrupting properties**

None of the ingredients is listed.

## 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:** Not hazardous for water.

## 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.

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**SECTION 14: Transport information**

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

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· **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.**