

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

- **1.1 Product identifier**
- **Trade name: KERA CASTING FAST**
- **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** Material for dental use
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dental Manufacturing S.p.a.  
Via Cà Mignola Nuova, 1699  
45021 - Badia Polesine (RO) - Italy  
Tel. +39 0425 51628 - Fax +39 0425 590156
- **Further information obtainable from:** info@ruthinium.it
- **1.4 Emergency telephone number:** Dental Manufacturing S.p.a. - Tel. +39 0425 51628 (Office Hours)

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xn; Harmful

R48/22: Harmful: danger of serious damage to health by prolonged exposure if swallowed.

- **Information concerning particular hazards for human 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.
- **Classification system:**  
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS08

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
cristobalite
- **Hazard statements**  
H373 May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**  
P260 Do not breathe dust/fume/gas/mist/vapours/spray.  
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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# Safety data sheet

## according to 1907/2006/EC, Article 31

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

#### · Dangerous components:

CAS: 14464-46-1 EINECS: 238-455-4	cristobalite	 Xn R48/22  STOT RE 2, H373	15 - 30%
CAS: 1309-48-4 EINECS: 215-171-9	magnesium oxide	substance with a Community workplace exposure limit	5 - 15%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **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.
- **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** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Prevent formation of dust.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

#### 1309-48-4 magnesium oxide

WEL	Long-term value: 10* 4** mg/m <sup>3</sup> (as Mg) *inhalable dust **fume and respirable dust
-----	--

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

- **8.2 Exposure controls**

- **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.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**

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 protection:** Not required.

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### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

Form:	Powder
Colour:	Whitish
· Odour:	Odourless
· Odour threshold:	Not determined.

· pH-value (10 g/l) at 20 °C: 6

##### · Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

##### · Ignition temperature:

Decomposition temperature: Not determined.

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

##### · Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not applicable.

· Density at 20 °C:	1.15 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.

· Solubility in / Miscibility with water: Insoluble.

· Partition coefficient (n-octanol/water): Not determined.

##### · Viscosity:

Dynamic:	Not applicable.
Kinematic:	Not applicable.

##### · Solvent content:

Organic solvents: 0.0 %

Solids content: 100.0 %

· 9.2 Other information: No further relevant information available.

### SECTION 10: Stability and reactivity

#### · 10.1 Reactivity

#### · 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions: No dangerous reactions known.

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- **10.4 Conditions to avoid**  
*The product is normally supplied in a stabilized form. Avoid excessive heat for long periods of time, the product can polymerize. Avoid heat, flames and other sources of ignition*
- **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 toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**  
*The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:*

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **12.2 Persistence and degradability** *Easily biodegradable*
- **12.3 Bioaccumulative potential** *Not worth-mentioning accumulating in organisms*
- **12.4 Mobility in soil** *No further relevant information available.*
- **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.*
- **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 together with household garbage. Do not allow product to reach sewage system.*
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*
- **Recommended cleansing agents:** *Water.*

### SECTION 14: Transport information

- |                                       |  |
|---------------------------------------|--|
| · <b>14.1 UN-Number</b>               |  |
| · <b>ADR, IMDG, IATA</b>              | UN3288   |
| · <b>14.2 UN proper shipping name</b> |  |
| · <b>ADR</b>                          | 3288 TOXIC SOLID, INORGANIC, N.O.S. (cristobalite) |

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· <b>IMDG, IATA</b>	<b>TOXIC SOLID, INORGANIC, N.O.S. (cristobalite)</b>
· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR, IMDG, IATA</b>	
	
· <b>Class</b>	6.1 Toxic substances.
· <b>Label</b>	6.1
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	III
· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Warning: Toxic substances.
· <b>Danger code (Kemler):</b>	60
· <b>EMS Number:</b>	F-A,S-A
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5 kg
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	E
· <b>UN "Model Regulation":</b>	UN3288, TOXIC SOLID, INORGANIC, N.O.S. (cristobalite), 6.1, III

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
This product is to be considered as a preparation according to EU-legislation.  
This surfactant complies with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them at their direct request or at the request of a detergent manufacturer.
- **Labelling according to Regulation (EC) No 1272/2008 GHS label elements**
- **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.  
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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**· Relevant phrases**

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

*R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed.*

**· Contact: ---****· Abbreviations and acronyms:**

*ADR: Accord européen sur le transport 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 Harmonized 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)*

*STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2*

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

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