

## Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.05.2024

Version number 7 (replaces version 6)

Revision: 09.05.2024

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

- **1.1 Product identifier**
- **Trade name: KERA CASTING FAST**
- **UFI: 7300-F05J-900W-AHFA**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Life cycle stages PW** Widespread use by professional workers
- **Application of the substance / the mixture** Material for dental use
- **Uses advised against** Any use other than those identified is not recommended.
- **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.

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

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Description:** Mixture of substances listed below with nonhazardous additions.

#### Dangerous components:

CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO <sub>2</sub> ) STOT RE 2, H373 Specific concentration limit: STOT RE 2; H373: C ≥ 10 %	60-80%
CAS: 14464-46-1 EINECS: 238-455-4	crystalite STOT RE 2, H373 Specific concentration limit: STOT RE 2; H373: C ≥ 10 %	5-15%
CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO <sub>2</sub> ) STOT RE 1, H372 Specific concentration limits: STOT RE 1; H372: C ≥ 10 % STOT RE 2; H373: 1 % ≤ C < 10 %	5-15%

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

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

##### General information:

Rescue workers must wear the protective equipment described in section 8.2 of this safety data sheet.

**IF INHALATED:** Supply fresh air; consult doctor in case of complaints.

**After skin contact:** Wash the skin with plenty of water

##### After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

##### After swallowing:

Rinse out mouth and then drink plenty of water.

If ingested do not induce vomiting, seek medical assistance showing the safety data sheet or the hazard label

#### 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.

Use fire extinguishing methods suitable to surrounding conditions.

#### 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Ammonia (NH<sub>3</sub>)

#### 5.3 Advice for firefighters

##### Protective equipment:

As in any fire, wear self-contained breathing apparatus and appropriate protective clothing including gloves and eye / face protection.

See Section 8 for information on personal protection equipment.

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### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Use respiratory protective device against the effects of fumes/dust/aerosol.  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to section 13.  
Pick up mechanically.
- **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**  
Prevent formation of dust.  
Ensure that suitable extractors are available on processing machines
- **Information about fire - and explosion protection:** The product is not flammable.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a dry place  
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further data; see section 1.2.

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

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

<b>CAS: 14808-60-7 Quartz (SiO<sub>2</sub>) (60-80%)</b>	
OEL	Long-term value: 0.1 mg/m <sup>3</sup>
<b>CAS: 14464-46-1 cristobalite (5-15%)</b>	
OEL	Long-term value: 0.1 mg/m <sup>3</sup>
<b>CAS: 1309-48-4 magnesium oxide (5-15%)</b>	
OEL	Short-term value: 10** mg/m <sup>3</sup> Long-term value: 4* 5** 10*** mg/m <sup>3</sup> *respirable dust **fume ***total inhalable dust

- **Regulatory information** OEL: 2021 CoP for the Safety, Health and Welfare at Work
- **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.
- **Individual protection measures, such as 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:**  
Use suitable respiratory protective device in case of insufficient ventilation.  
Short term filter device:  
ABEK

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Filter P2

- **Hand protection** The use of gloves is recommended as a preventive measure

- **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.

Butyl rubber, BR

Nitrile rubber, NBR

Natural rubber, NR

- **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.

Breakthrough time: &gt; = 480 min - Material thickness: &gt; = 0.7 mm

Breakthrough time: &gt; = 60 min - Material thickness: &gt; = 0.5 mm

Breakthrough time: &gt; = 30 min - Material thickness: &gt; = 0.2 mm

- **Eye/face protection** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Physical state**

Solid

- **Colour:**

Whitish

- **Odour:**

Odourless

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

&gt;1,400 °C

- **Boiling point or initial boiling point and boiling range**

Not applicable

- **Flammability**

Not applicable

- **Lower and upper explosion limit**

- **Lower:**

Not applicable

- **Upper:**

Not applicable

- **Flash point:**

Not applicable.

- **Auto-ignition temperature:**

Not applicable

- **pH**

Not applicable.

- **Viscosity:**

- **Kinematic viscosity**

Not applicable.

- **Dynamic:**

Not applicable.

- **Solubility**

- **water:**

Insoluble.

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure:**

Not applicable.

- **Density and/or relative density**

- **Density at 20 °C:**

1.15 g/cm<sup>3</sup>

- **Relative density**

Not determined.

- **Vapour density**

Not applicable.

- **Particle characteristics**

See section 3.

- **9.2 Other information**

- **Appearance:**

- **Form:**

Powder

- **Important information on protection of health and environment, and on safety.**

- **Ignition temperature:**

Product is not selfigniting.

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· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	100.0 %
· <b>Change in condition</b>	
· <b>Softening point/range</b>	
· <b>Oxidising properties</b>	Not applicable
· <b>Evaporation rate</b>	Not applicable.

· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No hazardous reactions when stored and handled according to instructions
- **10.2 Chemical stability** The product is stable under normal conditions of use and storage
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **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:**  
At a preheating temperature of 250-300°C: slight smell of ammonia

### 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.
- **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** May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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### · 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** Non significant accumulation in organisms

· **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:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## SECTION 13: Disposal considerations

### · 13.1 Waste treatment methods

#### · Recommendation

Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations. The assignment of the waste code is the user's responsibility, after determining the properties of the waste and the process generating it and after discussing it with the authorities responsible for disposal.

#### · Uncleaned packaging:

#### · Recommendation:

Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.

## 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, ADN, IMDG, IATA**

· **Class** Void

### · 14.4 Packing group

· **ADR, IMDG, IATA** Void

### · 14.5 Environmental hazards:

· **Marine pollutant:** No

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- |   |  |
|---|--|
| · <b>14.6 Special precautions for user</b>                            | Not applicable.                                      |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable.                                      |
| · <b>Transport/Additional information:</b>                            | Not dangerous according to the above specifications. |
| · <b>UN "Model Regulation":</b>                                       | Void   |

### SECTION 15: Regulatory information

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

Safety data sheet prepared in accordance with Regulation 1907/2006/EC Article 31, Regulation (EU) No 878/2020 as subsequent amendments.

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **National regulations:**

- **Information about limitation of use:**

Employment restrictions concerning juveniles must be observed.

- **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.

- **Relevant phrases**

H372 Causes damage to organs through prolonged or repeated exposure.

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

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

As required by Regulation 1272/2008/CE art. 9, the classification of this compound is based on the calculation method taken from the data of the single substances therein and from the experimental data of this compound where available (viewable in sections 9, 11 and 12 in this document).

Procedure used for the classification of the mixture

STOT RE 2, H373 - method of calculation

- **Version number of previous version: 6**

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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 Harmonised 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)

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*PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2*

IE