

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

#### 1.1. Product identifier

Product form : Mixture  
Trade name : CERA PALADAR  
Product code : 8548

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only  
Dental laboratories

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

FAMADENT S.L.U.  
Garrotxa, 6 Polígono Empordà Internacional  
ES- 17469 Vilamalla  
España  
T +34 972 526 169  
[protechno@protechno.com](mailto:protechno@protechno.com) - [www.protechno.com](http://www.protechno.com)  
E-mail address of competent person responsible for the SDS : [SDS@protechno.com](mailto:SDS@protechno.com)

#### 1.4. Emergency telephone number

Emergency number : +34 972 526 169

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

#### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. Risk of thermal burns on contact with molten product. Thermal burns : Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: If you feel unwell, seek medical advice.

### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Carbon dioxide.

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

Hazardous decomposition products in case of fire : No hazardous decomposition products known.

### 5.3. Advice for firefighters

Precautionary measures fire	: Use water stream to cool containers.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : If melted: allow liquid to solidify before taking it up. Ventilate spillage area.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment. Do not allow to enter drains or water courses.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Mechanically recover the product. If melted: allow liquid to solidify before taking it up.
Other information	: Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 13.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Use only by appropriate trained persons. Ensure good ventilation of the work station. Wear personal protective equipment. Keep in original containers closed. Avoid skin contact with hot material. Keep away from ignition sources.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool. Only store product in original container. Protect from sunlight.
- Storage temperature : 5 – 30 °C

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

No additional information available

##### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

###### Appropriate engineering controls:

Common hygienic measures in a dental laboratory. Ensure good ventilation of the work station.

##### 8.2.2. Personal protection equipment

###### Personal protective equipment symbol(s):



###### 8.2.2.1. Eye and face protection

###### Eye protection:

Safety glasses

###### 8.2.2.2. Skin protection

###### Skin and body protection:

Wear suitable protective clothing

###### Hand protection:

Use insulated gloves when handling this material hot. Nitrile rubber gloves

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### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: pink.
Odour	: Characteristic.
Odour threshold	: Not available
Melting point	: > 50 °C
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: > 140 °C
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: insoluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 0.9 g/cm <sup>3</sup>
Relative density	: Not applicable
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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### 10.4. Conditions to avoid

Heat. Direct sunlight.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

Viscosity, kinematic	Not applicable
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### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

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### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. Comply with local regulations for disposal.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR	IMDG	IATA	RID
<b>14.1. UN number or ID number</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>			
Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>			
Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available			

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

###### REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

###### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

###### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

###### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

###### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

###### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

###### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

###### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

#### Indication of changes:

SDS EU format according to COMMISSION REGULATION (EU) 2020/878.

#### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

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### Abbreviations and acronyms:

RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
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Data sources : Classification according to Classification, Labelling and Packaging of Substances and Mixtures (SEA) Regulation published in the Official Journal numbered 28848 on December 11, 2013. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.