

## MATERIAL SAFETY DATA SHEET

## PORCELAIN TEETH

### 1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

- 1.1 Product Name:** Porcelain Teeth
- 1.2 Trade Name:** ENTA CERAM classic porcelain  
ENTA CERAM polychrome porcelain  
ENTA CERAM optiform porcelain  
ENTA CERAM solution porcelain  
UNILUX porcelain  
REAL porcelain  
UNIVAC porcelain  
CERAFORM porcelain  
VF HARMONIQUE porcelain
- 1.3 Application/Use of the products:** Anterior and posterior denture teeth
- 1.4 Company/Manufacturer:** ENTA BV.  
Brouwerijbaan 10 4615 AA Bergen op Zoom, the Netherlands  
Tel: +31-(0)164-237.454 – [info@enta.nl](mailto:info@enta.nl)
- 1.5 Emergency information:** ENTA BV.  
Brouwerijbaan 10 4615 AA Bergen op Zoom, the Netherlands  
Tel: +31-(0)164-237.454 – [info@enta.nl](mailto:info@enta.nl)

### 2. COMPOSITION / INFORMATION ON INGREDIENTS – main components

- 2.1 Chemical composition:** Ceramic denture teeth of Feldspar, Quartz, Caoline and pigments

#### 2.1.1 Composition of Feldspar:

Chemical	SiO <sub>2</sub>	Al <sub>2</sub> O <sub>3</sub>	Na <sub>2</sub> O	K <sub>2</sub> O	Fe <sub>2</sub> O <sub>3</sub>	TiO <sub>2</sub>	CaO	MgO
Qty	65,16%	18,5%	3,4%	12,4%	<0,06%	0,02%	0,24%	0,22%

#### 2.1.2 Composition of Quartz:

Chemical	SiO <sub>2</sub>	Fe <sub>2</sub> O <sub>3</sub>	Al <sub>2</sub> O <sub>3</sub>
Qty	>99,55%	max 0,05%	max 0,40%

#### 2.1.3

Chemical	Al <sub>2</sub> O <sub>3</sub> .2SiO <sub>2</sub> .2H <sub>2</sub> O
Qty	1,5%

**2.2 Physical components**

Gold wires  
Platinum support

**2.3 Hazardous components:** None

**2.4 Further information:** None

### 3. HAZARDOUS IDENTIFICATION

**3.1 Hazard description:** The product presents no toxic hazard

**3.2 Chemical dangers:** None

**3.3 Physical dangers:** Grinding dust (see 8.2.3)

**3.4 Further information:** The product presents no toxic hazard when used according to the manufacturer's instructions. If a patient is known to be allergic to any of the ingredients of the teeth, the product should not be used

### 4. FIRST AID MEASURES

**4.1 Description of first aid measures**

<b>Eye contact with dust:</b>	Flush eyes with plenty of water; mechanical effects only
<b>Skin contact:</b>	No specific requirements
<b>Ingestions:</b>	Give large amounts of water
<b>Inhalation:</b>	No specific requirements

**4.2 Notes to medical doctor:** No specific antidote. Effects support therapy. Care should be effected according doctor's evaluation with respect to the patient's reactions

### 5. FIRE FIGHTING MEASURES

**5.1 Extinguishing media:** Dry chemical, CO2, water spray or regular foam



## 5.2 Special hazards arising from the substance

<b>Hazardous combustion products:</b>	None
<b>General hazard:</b>	Non-combustible
<b>Properties contributing to flammability:</b>	None
<b>Flash point:</b>	Not applicable
<b>Flammable limits in air:</b>	Upper: not available, Lower: not available
<b>Auto ignition temperature:</b>	Not applicable
<b>Sensitivity to static discharge:</b>	Not applicable
<b>Sensitivity to static impact:</b>	Not applicable

5.3 Advice for fire-fighters: None

## 6. ACCIDENTAL RELEASE MEASURES

6.1 Person related safety precautions:	Not required
6.2 Measures for environmental precautions:	Avoid dispersion
6.3 Measures for cleaning:	Clean up mechanically

## 7. HANDLING AND STORAGE

7.1 Precautions for safe handling:	Only adequate trained personnel should handle this product
7.2 Industrial hygiene:	Usual hygienic measures for dental practice
7.3 Conditions for safe storage:	Store in cool and dry place with no exposure to sunlight
7.4 Fire and explosion protection:	None

## 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1 Technical measures:	Provide adequate local ventilation
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## 8.2 Personal protective equipment

<b>8.2.1 Hand protection:</b>	None particular precaution should be taken with normal usage.
<b>8.2.2 Eyes protection:</b>	None particular precaution should be taken with normal usage. When the product is grinded or polished, use protective glasses.
<b>8.2.3 Respiratory protection:</b>	Not needed with normal usage. When product is grinded or polished, use localized aspiration of dusts and/or protective mask
<b>8.2.4 Other:</b>	None

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance:</b>	Solid, teeth
<b>Colour:</b>	Tooth shaded
<b>Odour:</b>	Odourless
<b>pH:</b>	Not applicable
<b>Melting point:</b>	Decomposes at 1400C
<b>Boiling point:</b>	Not applicable
<b>Flash point:</b>	Not applicable
<b>Evaporation rate:</b>	Not applicable
<b>Flammability:</b>	Not applicable
<b>Flammable limits:</b>	Not applicable
<b>Vapour pressure:</b>	Not applicable
<b>Vapour density:</b>	>6.0 g/cm <sup>3</sup>
<b>Specific gravity:</b>	Not applicable
<b>Solubility in water:</b>	Not soluble
<b>Partition coefficient n-octanol/water:</b>	Not applicable
<b>Auto ignition temperature:</b>	Not applicable
<b>Decomposition temperature:</b>	Not applicable
<b>Viscosity:</b>	Not applicable
<b>Explosive properties:</b>	Not explosive
<b>Oxidizing properties:</b>	Not an oxidizer

### 9.2 Other information

<b>Self reactive properties:</b>	Does not meet classification criteria
<b>Pyrophoric properties:</b>	Does not meet classification criteria
<b>Self heating properties:</b>	Does not meet classification criteria
<b>Water reactive properties:</b>	Does not meet classification criteria
<b>Corrosive to metals:</b>	Does not meet classification criteria
<b>Molecular weight:</b>	-

## 10. STABILITY AND REACTIVITY

- 10.1 Chemical stability: Stable
- 10.2 Reactivity: None
- 10.3 Possibility: None
- 10.4 Conditions to avoid: Stable in normal conditions
- 10.5 incompatible materials: None
- 10.6 Hazardous decomposition products: None when correctly utilized

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Toxic kinetics, metabolism and distribution

Non human toxicological data Not available

Method:

Doses:

Routes of administration:

Results:

Absorption:

Distribution:

Metabolism:

Excretion:

### 11.2 Information on toxicological effects

11.2.1 Acute toxicity: Not available

Substance	Oral	Dermal	Inhalation
Porcelain teeth	none	none	none

11.2.2 Skin corrosion/irritation: No classification

Substance Data

Porcelain teeth None

11.2.3 Serious eye damage/irritation: No classification

Substance Data

Porcelain teeth None

11.2.4 Respiratory or skin sensitization: No classification

Substance Data

Porcelain teeth Non-sensitizing

**11.2.5 Carcinogenicity, Mutagenicity, reproductive toxicity:**

Substance	Germ Cell Mutagenicity	Carcinogenicity	Reproductive toxicity
Porcelain teeth	Based on available data, the classification criteria are not met	Based on available data, the classification criteria are not met	Based on available data, the classification criteria are not met

**Carcinogenicity listings:** Not listed

**11.2.6 Specific target organ toxicity (STOT) – Single exposure**

Substance	Carcinogenicity
Porcelain teeth	Based on available data, the classifications are not met

**11.2.7 Specific target organ toxicity (STOT) – Repeated exposure**

Substance	Carcinogenicity
Porcelain teeth	Based on available data, the classifications are not met

**11.2.8 Aspiration hazard**

Substance	Carcinogenicity
Porcelain teeth	Based on available data, the classifications are not met

**12. ECOLOGICAL INFORMATION**

<b>12.1 Toxicity:</b>	Insoluble. No dangers for environment are known
<b>12.2 Persistence and degradability:</b>	The material is known to be stable in environment. Due to the low biodegradability the product should not reach water or ground
<b>12.3 Bio-accumulative potential:</b>	No data available for the product
<b>12.4 Mobility in soil:</b>	No data available for the product
<b>12.5 Other adverse effects:</b>	None

### 13. DISPOSAL CONSIDERATIONS

**13.1 Waste treatment methods:** Use a qualified waste disposal facility. Dispose of waste according to local laws and regulations

### 14. TRANSPORT INFORMATION

<b>14.1 Transport at land – road and railroad:</b>	Class ADR/RID	No dangerous cargo
UN Number:	None	
UN proper shipping name:	None	
Packing group	None	

<b>14.2 Transport at sea:</b>	Class IMDG	No dangerous cargo
UN Number:	None	
UN proper shipping name:	None	
Packing group:	None	

<b>14.3 Air transport:</b>	Class IATA-DGR	No dangerous cargo
UN Number:	None	
UN proper shipping name:	None	
Packing group:	None	
Subsidiary risk:	None	
Labels:	None	

<b>Passenger airplane</b>		No dangerous cargo
Packing instructions:	None	
Max. capacity	None	

<b>Cargo Airplane</b>		No dangerous cargo
Packing instructions	None	
Max. Capacity:	None	

**14.4 Further information** This product/medical device is not classified as dangerous In the meaning of transport regulations

## 15. REGULATORY INFORMATION

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

**European Union:** This product is a medical device according to the EC-directives

**15.2 Chemical safety assessment:** This products does not require classification as Dangerous Goods

## 16. TOXICOLOGICAL INFORMATION

This medical device has been studied and formulated for an exclusive professional dental use and must be used following instructions, procedures and precautions of use. The information disclosed in this Safety Data is believed to be correct to the best of our current knowledge and experience. It only relates to the specific product designated herein and it may not be valid when said product is used in combination with any other material or in any process, unless specified in the text. However, this document aims to provide the necessary health and safety information of the product and is not to be considered a warranty or quality specification and shall not establish any legally valid contractual relationship. Considering that used conditions and modes are not under our control we can't assume any responsibility for results that do not meet user's expectations. The manufacturer is not responsible for damages due to incorrect use or undue handlings. Furthermore, ENTA B.V. is not responsible for disposal or testing of this product for hazardous content, and will not be liable to any party for such disposal, testing, or content. This safety data sheet overrules and substitutes any previous edition.

### **For further information on the product:**

For further information consult the product datasheet. Before use, operators must be sure that the product characteristics are suitable to their needs.

### **Revision Summary:**

Revision # 1. All sections revised. New format. Regular review completed. This MSDS has been prepared to meet European Regulations (EC) and the applicable ISO standards.