

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 06.03.2015


Version number 3

Revision: 06.03.2015

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

- **1.1 Product identifier**
- **Trade name:** Ceram.X  
Ceram.X duo +  
Ceram.X mono +
- **Application:** Light curing composite
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Dental filling material
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
DENTSPLY DeTrey GmbH  
De-Trey-Str. 1  
D-78467 Konstanz  
GERMANY  
Tel.: +49-(0)7531-583-0  
Fax: +49-(0)7531-583-104  
email: KonstanzDEU.info-sdb@dentsply.com
- **Further information obtainable from:**
  - Departement Analytical Research / Research & Development for technical information
  - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.
  - **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**  
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.  
The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
  - **Hazard-determining components of labelling:**  
Ethoxylated Bisphenol A Dimethacrylate
  - **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.
  - **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

(Contd. on page 2)

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(Contd. of page 1)

- P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P321 Specific treatment (see on this label).  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 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.

### SECTION 3: Composition/information on ingredients

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

#### · **Dangerous components:**

41637-38-1	Ethoxylated Bisphenol A Dimethacrylate	10-<25%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	

- **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** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing** Seek medical treatment.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** 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.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

(Contd. on page 3)

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(Contd. of page 2)

- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **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** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **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 only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **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:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
Do not eat or drink while working.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**  
Natural rubber, NR  
Recommended thickness of the material:  $\geq 0.12$  mm  
Permeation: Level  $\geq 1$

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.

(Contd. on page 4)

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(Contd. of page 3)

- **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:** *Safety glasses*
- **Body protection:** *Protective work clothing.*

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

<b>Form:</b>	<i>paste</i>
<b>Colour:</b>	<i>According to product specification</i>
<b>Odour:</b>	<i>Characteristic</i>
<b>Odour threshold:</b>	<i>Not determined.</i>

· **pH-value:** *Not determined.*

##### · Change in condition

<b>Melting point/Melting range:</b>	<i>undetermined</i>
<b>Boiling point/Boiling range:</b>	<i>Undetermined.</i>

· **Flash point:** *Not applicable*

· **Flammability (solid, gaseous)** *Not applicable.*

##### · Ignition temperature:

**Decomposition temperature:** *Not determined.*

· **Self-igniting:** *Product is not selfigniting.*

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

##### · Explosion limits:

<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined.</i>

· **Vapour pressure:** *Not determined.*

<b>Density:</b>	<i>Not determined</i>
<b>Relative density</b>	<i>Not determined.</i>
<b>Vapour density</b>	<i>Not determined.</i>
<b>Evaporation rate</b>	<i>Not determined.</i>

##### · Solubility in / Miscibility with

**Water:** *Not miscible or difficult to mix*

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

##### · Viscosity:

<b>dynamic:</b>	<i>Not determined.</i>
<b>kinematic:</b>	<i>Not determined.</i>

##### · Solvent content:

**Organic solvents:** *0.0 %*

(Contd. on page 5)

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(Contd. of page 4)

· **9.2 Other information** *No further relevant information available.*

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** *No further relevant information available.*
- **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*
- **10.4 Conditions to avoid** *No further relevant information available.*
- **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:**  
*Irritant to skin and mucous membranes.*  
*The unpolymerized product may be irritant to the skin for susceptible persons.*
- **on the eye:** *Irritating effect.*
- **Sensitisation:**  
*Sensitisation possible through skin contact.*  
*Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.*
- **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.*  
*Irritant*

**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.*
- **Additional ecological information:**
- **General notes:**  
*Do not allow product to reach ground water, water course or sewage system.*  
*Danger to drinking water if even small quantities leak into the ground.*
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*
- **12.6 Other adverse effects** *No further relevant information available.*

GB

(Contd. on page 6)

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(Contd. of page 5)

### 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.

- European waste catalogue

18 01 06\* chemicals consisting of or containing dangerous substances

- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |  |                 |
|--|-----------------|
| · 14.1 UN-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              |
| · 14.6 Special precautions for user  | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation":   | -               |

### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
No further relevant information available.
- 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 attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

(Contd. on page 7)

GB

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(Contd. of page 6)

*For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.*

· **Relevant phrases**

*H315 Causes skin irritation.*

*H317 May cause an allergic skin reaction.*

*H319 Causes serious eye irritation.*

*H335 May cause respiratory irritation.*

· **Department issuing MSDS: Analytical Research**

· **Contact: HotLine for urgent technical support: +49-7531-583-350**

· **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 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)*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2*

*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*

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

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