

Safety data sheet

According to 91/155 EEC

Printing date 03/10/2011

Version number 1

Revision: 03/07/2011

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**

- **Trade name:** Ceram X
Ceram.X duo +
Ceram.X mono +

- **Application:** Light curing composite
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Dental filling material

- **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

Supplier for CANADA:
Dentsply Canada
161 Vinyl Court
Woodbridge, ON L4L4A3

Tel.: (905) 851 6060 or 1-800-263-1437
Fax: (905) 851-9809

- **Further information obtainable from:**

- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets

- **Emergency telephone number:** +49-(0)7531-583-0

2 Composition/information on ingredients

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

- **Dangerous components:**

41637-38-1	Dimethacrylate Resin	Xi R36/37/38; Xi R43	10-25%
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- **Additional information** For the wording of the listed risk phrases refer to section 16.

3 Hazards identification

- **Classification of the substance or mixture**

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

R43: May cause sensitisation by skin contact.

- **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.

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CDN

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- **Label elements**

- **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

- **Code letter and hazard designation of product:**



Xi Irritant

- **Hazard-determining components of labelling:**

Dimethacrylate Resin

- **Risk phrases:**

43 May cause sensitisation by skin contact.

- **Safety phrases:**

23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).

24 Avoid contact with skin.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

37 Wear suitable gloves.

60 This material and its container must be disposed of as hazardous waste.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** *Not applicable.*

- **vPvB:** *Not applicable.*

4 First aid measures

- **Description of first aid measures**

- **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.*

5 Firefighting measures

- **Extinguishing media**

- **Suitable extinguishing agents**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **For safety reasons unsuitable extinguishing agents** *Water with full jet.*

- **Advice for firefighters**

- **Protective equipment:** *Wear self-contained respiratory protective device*

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** *Wear protective clothing.*

- **Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.*

- **Methods and material for containment and cleaning up:** *Ensure adequate ventilation.*

- **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.

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7 Handling and storage

- **Handling** Product is intended for dental use only.
- **Precautions for safe handling** Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

8 Exposure controls/personal protection

- **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.
- **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.

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

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: *paste*
Colour: *According to product specification*
Odour: *Characteristic*

· **Change in condition**

Melting point/Melting range: *undetermined*

· **Flash point:** *Not applicable*

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

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

· **Density:** *Not determined*

· **Solubility in / Miscibility with**

Water: *Not miscible or difficult to mix*

10 Stability and reactivity

· **Reactivity**

· **Chemical stability**

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

· **Possibility of hazardous reactions** *No dangerous reactions known*

· **Hazardous decomposition products:** *No dangerous decomposition products known*

11 Toxicological information

· **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.*

· **Sensitization:**

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

12 Ecological information

· **Toxicity**

· **Acquatic toxicity:** *No further relevant information available.*

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

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

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

13 Disposal considerations

- **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.

14 Transport information

- **TDG (Transport dangerous goods):**
- **TDG class:** -

- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No

- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

- **Special precautions for user** Not applicable.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations**
- **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

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

- **Department issuing MSDS:** Analytical Research
- **Contact:** HotLine for urgent technical support: +49-7531-583-333