

**DENTSPLY/International**  
**DENTSPLY/Caulk**  
**Safety Data Sheet**

596899

**1. Identification**

Product Name <b>Ceram•X<sup>®</sup> Mono<sup>+</sup> Nano Ceramic Restorative</b>	SDS Code Number <b>596899</b>
Trade Name & Synonyms <b>Ceram•X<sup>®</sup> Mono<sup>+</sup> Nano Ceramic Restorative</b>	Date of Last Revision <b>11/11/10</b>
Manufactured for: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a>    <a href="http://www.dentsply.com">http://www.dentsply.com</a></b>
Grades or Minor Variant Identities <b>Includes Compules<sup>®</sup> and Syringes</b>	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) <b>Light Curing Composite/Dental Filling Material</b>	Emergency Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>

**2. Hazard(s) Identification**



WARNING  
CAUSES SKIN IRRITATION

Wash hands thoroughly after handling.  
Wear protective gloves.  
If on skin: Wash with plenty of soap and water.  
If skin irritation or rash occurs: Get medical attention  
Wash contaminated clothing before reuse  
Dispose of contents/container in accordance with local regulations

**3. Composition/Information on Ingredients**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Barium boron alumino silicate glass	65997-17-3	10 mg/m <sup>3</sup>	< than 80
Silicon Dioxide - Amorphous	112945-52-5	3 mg/m <sup>3</sup>	< than 5
Polymerizable dimethacrylate resins	24448-20-2	N.E.	< than 25

Other Information: Colorants are synthetic inorganic iron oxides, sodium-alumino-sulfo-silicate and titanium dioxide.

**4. First Aid Measures**

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable
Ingestion	Not Applicable	Not Applicable	Not Applicable
Mucosa	Rinse tissue for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable

Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.

**5. Fire Fighting Measures**

Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: CO <sub>2</sub> , extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins.			
Product does not present an explosion hazard.			

**6. Accidental Release Measures**

Containment Techniques: Material is a paste and as such will not flow.
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.
Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable
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## 7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

## 8. Exposure Control / Personal Protection



Occupational Exposure Limits: Not Applicable		
Engineering Controls: Not Applicable		
Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required	Not Applicable
Body Protection	Protective work clothing	Not Applicable

## 9. Physical and Chemical Characteristics

Appearance: Various shades of viscous paste.		Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: Very High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 2.2 g/cm <sup>3</sup>	Solubility in Water: Not soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable, Product will not autoignite.
Other: Not Applicable		

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.		
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known	

## 11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant. Emergency Overview Material is irritating to eyes, respiratory system and skin.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is not harmful if swallowed using clinically relevant quantities	Not Applicable	Mild	Not Applicable	Not Applicable
Mucosa	Material can cause irritation.	Single	Mild	Inflammation of the mucosa	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0					

## 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class I (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.
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### 13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

### 14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

### 15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations
<u>Section 313 Toxic Chemicals</u> : This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65</u> : This product does not contain any chemicals, which are on the California Proposition 65 list.
<u>International Regulations: Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

### 16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products 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.
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