

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

**574898**

**1. Product and Company Identification**

Product Name <b>Principle®</b>	SDS Code Number <b>574898</b>
Trade Name & Synonyms <b>Principle® Self-Adhesive Compomer Cement Powder</b>	Date of Last Revision <b>05/16/13</b>
Manufacturer <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 Not Applicable	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) Not Applicable	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 occurs: Get Medical Advice/attention.  
Take off contaminated clothing and wash before reuse.**

**3. Composition/Information on Ingredients**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Strontium aluminum fluorosilicate glass	65997-18-4	Not Established	> 90
Sodium Fluoride	7681-49-4	Not Established	< 5

Other Information: Colorants are synthetic inorganic iron oxides.

**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. Then consult physician.	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly.	Not Applicable	Not Applicable
Inhalation	Supply fresh air, consult physician if complaint persist.	Not Applicable	Not Applicable
Ingestion	Rinse mouth out and then drink plenty of water. If symptoms persist consult physician.	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable

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

**5. Fire and Explosion Data**

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: NFPA Flammability =0	
Extinguishing Media: Water spray, CO <sub>2</sub> , or extinguishing powder. 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: In routine use this product does not present an explosion hazard.			

**6. Accidental Release Measures**

Containment Techniques: Material is a solid and as such containment is limited to steps to reduce dust.
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Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Keep exposure to airborne particles to a minimum when cleaning by using proper ventilation as discussed in section 8.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

## 7. Handling and Storage

Handling Practices and Warnings: Minimize dust generation when handling. Avoid inhalation of dust, and contact with eyes. 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. To prevent water absorption and contamination. Store away from food and beverages.

## 8. Exposure Control / Personal Protection



Ventilation: None required.		Other Engineering Controls: Not Applicable
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE 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
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Wear protective gloves. Use a NIOSH or European Standard EN149 approved respirator to prevent inhalation of dust.		
Other Protective Measures and Equipment: Not Applicable.		

## 9. Physical and Chemical Characteristics

Appearance: Off-white powder.		Odor: Mild odor.
Normal Physical State: Solid		Melting Point: Not Applicable
Specific Gravity: 3.0g/cm <sup>3</sup>	Solubility in Water: Partially soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1) Not Applicable	Evaporation Rate (Butyl Acetate =1) Not Applicable
Other: Not Applicable		

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong acids, strong oxidizing agents.		
Hazardous Products Produced During Decomposition: No dangerous decomposition products known.		
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 may be irritating to the skin. On the eye the product has an irritating effect.					
Emergency Overview: Powder is not known to cause significant health problems. Should be considered an inert or nuisance dust. Avoid inhalation of dust. Keep dust out of eyes to prevent irritation.					
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 may cause slight transient (temporary) irritation.	Single & Repeated	Mild	Irritation and possible corneal damage due to the powders used in the product.	Not Applicable
Skin	Material may be an irritant after repeated and prolonged exposure.	Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is probably not harmful if swallowed	Not Applicable	Mild	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure: Existing respiratory conditions may be aggravated by inhalation of powders.					
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: Not considered hazardous to surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 1					

## 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Generally not hazardous for water.

## 13. Disposal Considerations

Regulations: Smaller quantities can be disposed of with household waste. Dispose of in accordance with Federal, State and Local regulations.

Properties (Physical/Chemical) Affecting Disposal: Dry powder. 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
Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
Section 302 Extremely Hazardous Substances (TPQ): None
EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations <u>California Proposition 65</u> : This product does not contain any chemicals, which are on the California Proposition 65 list.
International Regulations: <u>Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements.
European Community Labeling: in accordance with EC Directives: Not a dangerous preparation.
International Regulations: Relevant R-phrases: R36/37/38 Irritating to eyes, respiratory system and skin.
European Inventory of New and Existing Chemicals Substances (EINECS):
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.

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

**1. Product and Company Identification**

Product Name <b>Principle®</b>	MSDS Code Number <b>574898</b>
Trade Name & Synonyms <b>Principle® Self-Adhesive Compomer Cement Liquid</b>	Date of Last Revision <b>05/16/13</b>
Manufacturer <b>DENTSPLY/Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com, http://www.dentsply.com</b>
Grades or Minor Variant Identities Not Applicable	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
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**2. Hazard(s) Identification**



**WARNING**  
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**Wash hands thoroughly after handling.**  
**Wear protective gloves.**  
**IF ON SKIN: Wash with plenty of soap and water.**  
**If skin irritation occurs: Get Medical Advice/attention.**  
**Take off contaminated clothing and wash before reuse.**

**3. Composition/Information on Ingredients**

Hazardous Components	C.A.S. Number	Exposure Limits	%
Bis-GMA	1565-94-2	Not Established	< 50
Triethylene Glycol Dimethacrylate	109-18-0	Not Established	< 30
Polymerizable dimethacrylate carboxylic acid resin	159002-30-9	Not Established	< 20
Dipentaerythritol pentaacrylate phosphate	87699-25-0	Not Established	< 15

**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. Consult a physician immediately.	Get medical aid.	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly.	Get medical aid if symptoms persist.	Not Applicable
Inhalation	Supply fresh air. If symptoms persist, consult physician.	Get medical aid.	Not Applicable
Ingestion	Drink plenty of water and provide fresh air. Do not induce vomiting. Consult a physician immediately.	Get medical aid.	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable

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

**5. Fire and Explosion Data**

Flashpoint Method: <b>Not Applicable</b>	Flammable (Explosive) Limits in Air LEL: Not Applicable    UEL: Not Applicable	Autoignition Temperature: Not Applicable	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: NFPA Flammability =0	
Extinguishing Media: Water spray, CO <sub>2</sub> , or extinguishing powder. 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: For Liquid: Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). For Gel, since material is a paste, scoop up bulk material and place in a suitable waste container.		
Spill/Leak Clean-up Procedures and Equipment: Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). Scoop up bulk material and place in a suitable waste container.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

## 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. Store away from food and beverages.

## 8. Exposure Control / Personal Protection



Ventilation: None required.		Other Engineering Controls: Not Applicable
Routes of Entry	Personal Protective Equipment (PPE) for Normal Use	PPE 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
General Hygiene Considerations and Work Practices: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at end of work. Avoid contact with the eyes and skin.		
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not Applicable		
Other Protective Measures and Equipment: Not Applicable.		

## 9. Physical and Chemical Characteristics

Appearance: Light yellow liquid		Odor: Faint acidic odor.
Normal Physical State: Liquid		Melting Point: Not Applicable
Specific Gravity: 1.3 g /cm <sup>3</sup>	Solubility in Water: Slightly soluble	pH: < 2
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1) Not Applicable	Evaporation Rate (Butyl Acetate =1) Not Applicable
Other: Not Applicable		

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Visible light, high temperatures, strong acids and oxidizing agents.		
Hazardous Products Produced During Decomposition: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins.		
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: High temperature, Sunlight	
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: High temperature, Sunlight	

## 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. Material is an organic corrosive acid and as such is irritating to skin and mucous membranes.					
Emergency Overview: Material is acidic.					
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 may cause irritation.	Single & Repeated	Severe	Irritation and possible corneal damage due to the acidic nature of product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Moderate to severe depending on contact time.	Irritation due to the acidic nature of the product.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Moderate	Irritation due to the acidic nature of the product.	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure: Existing respiratory conditions may be aggravated by inhalation of powders.					
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: Not considered hazardous to surface or ground water.
NFPA Hazard Classification Ratings (Scale 0-4), Health = 2, Fire = 0, Reactivity = 0

## 12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, streams or sewage systems.
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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. These R and S phrases apply to powder and liquid: R36/38 Irritating to eyes and skin. R51/53 Toxic to aquatic organisms may cause long-term effects in the environment. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of water. S37 Wear suitable gloves. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste. These R and S phrases apply to catalyst: R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms may cause long-term effects in the environment. S24 Avoid contact with skin.
<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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