

# DentsplySirona Safety Data Sheet

#### 1. Identification

Product Name	SDS Code Number	
Calibra® Ceram	507804	
Substance Identity	Date of Last Revision	
Calibra® Ceram Adhesive Resin Cement	10/23/17	
Manufacturer:	Address	
DENTSPLY Caulk	38 West Clarke Avenue	
	Milford DE 19963-1805	
	http://www.caulk.com http://www.dentsply.com	
Grades or Minor Variant Identities	Company Telephone Number (Product Inquiries)	
Not Applicable	(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)	
Product Use (for Canada)	Emergency Telephone Number	
Dual Curing Dental Luting Cement	CHEMTREC: 1-800-424-9300 (24 hours)	
	(Outside U.S. +1-703-527-3887) CCN6510	

# 2. Hazard(s) Identification



# WARNING MAY CAUSE AN ALLERGIC SKIN

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 – Base Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Urethane Dimethacrylate Resin	105883-40-7	Not Established	< 10
Polymerizable trimethacrylate resin	3290-92-4	Not Established	< 10
Polymerizable dimethacrylate resin	41637-38-1	Not Established	< 10
Polymerizable dimethacrylate resin	109-16-0	Not Established	< 5
Polymerizable dimethacrylate resin	868-77-9	Not Established	< 10
Polymerizable dimethacrylate resin	1709-71-3	Not Established	< 5

Other Information: Colorants are inorganic iron oxides.

# 3. Composition/Information on Ingredients - Catalyst Paste

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Hazardous Components	C.A.S. Number	Exposure Limits	%
Urethane Dimethacrylate Resin	105883-40-7	Not Established	< than 10
Urethane Modified Bis-GMA Dimethacrylate Resin	41637-38-1	Not Established	< than 10
Polymerizable Dimethacrylate Resins	3290-92-4/109-16-0	Not Established	< than 15
Dipentaerythritol Pentaacrylate Phosphate	87699-25-0	Not Established	< than 10

# 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.	Not Applicable	Not Applicable
	If symptoms persist consult physician		
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.	Not Applicable	Not Applicable
	If symptoms persist consult physician		
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.			

**5. Fire Fighting Measures** 

Flame Propagation or Burning Rate	Properties Contributing to Fire Intensity	Flammability Classification: Not Applicable	Other: Not Applicable
(for Solids) Not Applicable	Not Applicable	, , , , , , , , , , , , , , , , , , ,	II
Extinguishing Media: CO <sub>2</sub> , extinguishing powder, foam carbon dioxide or water  Extinguishing Media to Avoid: Water with full jet.			
spray. Fight larger fires with water spray or alcohol resistant foam.			
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

Containmen	Containment Techniques: Material is a paste and as such will not flow.				
Spill/Leak	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 gros	Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.				
Evacuation	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. 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: Creamy viscous paste. Multiple sh	Odor: Characteristic sweet acrylic ester odor.	
Normal Physical State: High Viscosity Liquid (	Paste)	Melting Point: Not Applicable
Specific Gravity: 1.8-1.9 g/cm <sup>3</sup> Solubility in Water: Not soluble		pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable		Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint Method: Not Applicable Flammable (Explosive) Limits in Air		Autoignition Temperature: Not Applicable,
LEL: Not Applicable UEL: 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: May Occur May Not Occur Conditions to Avoid: None known			
Stability? ⊠Stable ☐Unstable	r = r = r		

# 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.

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Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health Effect(s)	Target Organ(s)
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)		
Eye	Material can cause	Single	Moderate	Irritation and possible corneal damage	Not Applicable
	irritation.				
Skin	Material may be an	Single & Repeated	Moderate	Irritation or possible allergic response.	Not Applicable
	irritant			Severe allergic response may result in	
				breathing difficulties.	
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

Ingestion	Material is not harmful if	Not Applicable	Mild	Not Applicable	Not Applicable
	swallowed using clinically				
	relevant quantities				
Mucosa	Material can cause	Single	Mild	Inflammation of the mucosa	Not Applicable
	irritation.				
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	y NTP?: Not listed	IARC monograp	ohs?: Not listed OSF	HA regulated?: No All components of this pr	roduct 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 class1 (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.

#### 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	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

# **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: CERCLA 103 Reportable Quantity: 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 212 Toxic Chamicals. This product contains the following chamicals subject to Appual Paleoca Penerting Peculirements Under SARA Title III.

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.

 $\underline{U.S.\ State\ Regulations\ California\ Proposition\ 65:}\ This\ product\ does\ not\ contain\ any\ chemicals,\ which\ are\ on\ the\ California\ Proposition\ 65\ list.$ 

International Regulations: Canadian Environmental Protection Act:

This product is a medical device and not subject to chemical notification requirements.

European Community Labeling: Not a dangerous preparation.

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.