

DentsplySirona Safety Data Sheet

1. Identification

Product Name	SDS Code Number
Calibra [®] Universal	507806
Substance Identity	Date of Last Revision
Calibra® Universal Self-Adhesive Resin Cement	02/07/18
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	http://www.dentsplysirona.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



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 (Treat	ing, Testing and Monitoring): Treat symptomatically.	<u>.</u>	

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		
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water		Extinguishing Media to Avoid: Water with full j	et.
spray. Fight larger fires with water spr	ray 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.			S.
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			

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: 1	Not Applicable			
Individual Protection Personal Protective Equipment for Normal Use Personal Protective Equipment for Emergencie Measures				
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 sha	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 ³	Solubility in Water: Not soluble	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Pressure (mm Hg): Not Applicable Vapor Density (AIR=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 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		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 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	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 Condi	tions Aggravated by Exposure	Open sores and wounds	of the skin. Individuals	with known sensitivity to methacrylates, acr	rylates, 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 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 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 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.