

# DentsplySirona Safety Data Sheet

#### 1. Identification

Product Name	SDS Code Number
CALIBRA® Veneer Esthetic Resin Cement	507803
Substance Identity	Date of Last Revision
CALIBRA® Veneer Esthetic Resin Cement	03/16/17
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	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
Visible Light Curing Dental Veneer Cement	CHEMTREC: 1-800-424-9300 (24 hours)
6 1 1 1 6 1 1 1 6 1 1 1 1 1 1 1 1 1 1 1	(Outside U.S. +1-703-527-3887) CCN6510

# 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 - Base Shade

Hazardous Components	C.A.S. Number	Exposure Limits	%
Barium boron fluoro alumino silicate glass	65997-18-4	$10 \text{ mg/m}^3$	< than 70
Bis-GMA	1565-94-2	Not Established	< than 20
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 15
Hydrophobic Amorphous Silica	67762-90-7	$3 \text{ mg/m}^3$	< than 5

Other Information: Colorants are inorganic iron oxides 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.	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		
Extinguishing Media: CO <sub>2</sub> , extinguishing powder, foam carbon dioxide or water		Extinguishing Media to Avoid: Water with full jo	et.
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

ı	Containment Techniques: Material is a paste and as such will not flow.
ſ	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 ac	dequate ventilation.
Evacuation Procedures: Not Applicable Special Instructions: Not Applicable Reporting Requirements: 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: No	t 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 sha	Odor: Characteristic sweet acrylic ester odor.	
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 1.8 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		Autoignition Temperature: Not Applicable,
LEL: Not Applicable UEL: Not Appl		Product will not autoignite.
Other: Not Applicable		

# 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials.		l
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.		l
Hazardous Polymerization: May Occur May Not Occur Conditions to Avoid: None known		l
Stability? ⊠Stable ☐Unstable	Conditions to Avoid: None known	1

# 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.

	verview Material is irritating to			A . 1.01 . II 11 E00 .//	m : 0 ()
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 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.



# DentsplySirona Safety Data Sheet

# 1. Identification

Product Name	SDS Code Number
CALIBRA® Veneer Try-In Paste	507805
Substance Identity	Date of Last Revision
CALIBRA® Veneer Esthetic Resin Cement Try-In Paste	03/16/17
Manufacturer:	Address
DENTSPLY Caulk	38 West Clarke Avenue
	Milford DE 19963-1805
	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
Not Applicable	CHEMTREC: 1-800-424-9300 (24 hours)
	(Outside U.S. +1-703-527-3887) CCN6510

# 2. Hazard(s) Identification



# WARNING CAUSES MILD SKIN IRRITATION

If irritation occurs: Get medical advice/attention

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Glycerine	56-81-5	$10 \text{ mg/M}^3$	> than 70
Amorphous Fumed Silica	7631-86-9	2 mg/M <sup>3</sup>	< than 20
Titanium Dioxide	13463-67-7	10 mg/M <sup>3</sup>	< than 2

Other Information: Colorants are inorganic iron oxides.

# 3. Hazard Identification

Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.					
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)
Eye	Material may cause slight transient (temporary) irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the fillers 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	Vapors are minimal due to physical properties.	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 Cor	Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.				
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 = 0, Reactivity = 0					

# 4. First Aid Measures

Routes of	First Aid Instructions	Immediate Medical	Delayed Effects
Exposure		Attention	
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	Supply fresh air, consult physician if symptoms persist.	Not Applicable	Not Applicable
Ingestion	If symptoms persist consult physician. Do not induce vomiting unless	Not Applicable	Not Applicable
	instructed to do so by medical personnel.		
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physicia	ans (Treating, Testing and Monitoring): Treat symptomatically.		

5. Fire and Explosion Data

Flashpoint Method: 390°F (199°C) for	Flammable (Explosive) Limits in Air	Autoignition Temperature:	Other: Not	
Glycerine. Pensky-Martin Closed Cup	LEL: Not Applicable UEL: Not Applicable	698°F (370°C)	Applicable	
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Intensity: Not	Flammability Classification:		
Solids) Not Applicable	Applicable	Not Applicable		
Extinguishing Media: CO <sub>2</sub> , Water fog or fine sp	Extinguishing Media to Avoid: W	Vater with full		
Type).	jet.			
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.				
Unusual Fire and Explosion Hazards: During a fire, smoke may contain glycerine in addition to unidentified toxic and/or irritating compounds. Hazardous				
combustion products may include but not limited to aldehydes, carbon monoxide and carbon dioxide.				

# 6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.			
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal 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. Glycerine freezes at 64°F (18°C). Product should be kept above 64°F (18°C) but less than 130°F (54°C).

# 8. Exposure Control / Personal Protection









Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures		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
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Creamy viscous paste. Multiple shades.		Odor: Mild odor.
Normal Physical State: High Viscosity Liquid (Paste)		Melting Point: Not Applicable
Specific Gravity: 1.4 g/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): N A
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

# 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials such as Sodium Hypochlorite or Hypochlorous Acid		
Hazardous Products Produced During Decomposition: Acrolein.		
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, Carcinogenicit	y, Neurological Effects	, Genetic Effects, Reproduct	ive Effects, or Structure Activity Dat	ta:
For ingestion,	the LD <sub>50</sub> for glycerine in Rats is 17,000	0 - 27,000  mg/Kg.			
Emergency Ov	erview: Material may be mildly irritate	ting to eyes.			
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	Moderate	Irritation and possible corneal damage due to the fillers 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	Vapors are minimal due to physical properties.	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 Open sores and wounds of the skin.

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: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.

NFPA Hazard Classification Ratings (Scale 0-4), Health = 0, 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. 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: <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

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>U.S. State Regulations California Proposition 65:</u> 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.