## **SAFETY DATA SHEETS**

# This SDS packet was issued with item: 070460352

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070460311 070460329 070460337 070460345 071705045

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071017052



## DentsplySirona Safety Data Sheet

#### 1. Identification

Product Name	SDS Code Number
CALIBRA <sup>®</sup> Veneer Esthetic Resin Cement	507803
Substance Identity	Date of Last Revision
CALIBRA <sup>®</sup> Veneer Esthetic Resin Cement	01/03/20
Manufacturer:	Address
DENTSPLY Milford	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
Visible Light Curing Dental Veneer Cement	CHEMTREC: 1-800-424-9300 (24 hours)
	(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 Attent		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

Properties Contributing to Fire Intensity	Flammability Classification: Not Applicable	Other: Not Applicable	
Not Applicable			
ning powder, foam carbon dioxide or water	Extinguishing Media to Avoid: Water with full j	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.			
	Not Applicable ning powder, foam carbon dioxide or water ray or alcohol resistant foam. nters: Firefighters should wear self-contained re Formation of toxic, irritating gases is possible f	Not Applicable If   ning powder, foam carbon dioxide or water ray or alcohol resistant foam. Extinguishing Media to Avoid: Water with full just or alcohol resistant foam.   nters: Firefighters should wear self-contained respiratory protective devices. Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resin	

## 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: No	t Applicable				
Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies			
Measures					
Eye/Face	Safety Glasses Not Applicable				
Skin	The glove material has to be impermeable and	Not Applicable			
resistant to the product.					
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 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 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 danger	ous 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**

		11.10410	ological fillor il	lation	
Toxicity Data,	Epidemiology Studies, Carcin	ogenicity, Neurological E	Effects, Genetic Effects,	Reproductive Effects, or Structure Activity	Data:
Product is an ir	ritant to the skin and mucous	membranes. The unpolym	nerized product may be	an irritant to the skin in susceptible persons.	On the eye the
product has an	irritating effect. Sensitization:	Repeated or prolonged c	ontact with the unpolym	nerized material may cause sensitization for	persons allergic to
acrylates and n	nethacrylates. This product sho	ows the following dangers	s according to internally	approved calculation methods for composit	e materials: Irritant.
Emergency Ov	erview 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	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 Condi	tions Aggravated by Exposure	Open sores and wounds	of the skin. Individuals	with known sensitivity to methacrylates, acr	ylates, or urethane
dimethacrylate	resin used in Dental restorativ	ve products.			
Carcinogenicity	y NTP?: Not listed	IARC monograp	ohs?: Not listed OSH	HA regulated?: No All components of this pr	oduct are in
compliance wit	th the inventory listing Require	ements of the U.S. Toxic	Substances Control Ac	t (TSCA) Chemical Substance Inventory.	
Potential Envir	onmental Effects Do not allow	v to enter sewers/ surface	or ground water.		
NFPA Hazard	Classification Ratings (Scale (	(-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 (Selfassessment): 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: <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.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.