# DentsplySirona Safety Data Sheet



#### 1. Identification

1. Iucinincation			
Product Name	SDS Code Number		
Amalgam Bonding Base and Catalyst	534498		
Substance Identity	Date of Last Revision		
Amalgam Bonding	11/04/19		
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		
Dental Bonding Agent	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 or rash occurs: Get medical attention Wash contaminated clothing before reuse Dispose of contents/container in accordance with local regulations

# **3.** Composition/Information on Ingredients – Base Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Ethoxylatedbisphenol A dimethacrylate	41637-38-1	Not Established	< than 50
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 40
Bis-GMA	1565-94-2	Not Established	< than 20

# 3. Composition/Information on Ingredients – Catalyst Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Ethoxylatedbisphenol A dimethacrylate	41637-38-1	Not Established	< than 50
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 40
Bis-GMA	1565-94-2	Not Established	< than 20
Benzoyl peroxide	94-36-0	$5 \text{ mg/m}^3$	< than 5

# 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 jet.		
	spray. Fight larger fires with water spray or alcohol resistant foam.			
ſ	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: 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: N	Not Applicable		
Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment	
Measures		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: Base is light beige colored, clear liquid. Catalyst is clear liquid.		Odor: Characteristic sweet acrylic ester odor.		
Normal Physical State: Low viscosity liquid.		Melting Point: Not Applicable		
Specific Gravity: 1.1 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 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 swallowed using clinically relevant quantities	Not Applicable	Mild	Not Applicable	Not Applicable
Mucosa	Material can cause irritation.	Single	Mild	Inflammation of the mucosa	Not Applicable

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 (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: Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements. <u>European Community Labeling</u>: 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.