

DentsplySirona Safety Data Sheet

1. Identification

Product Name	SDS Code Number
Esthet•X [®] HD	530699
Substance Identity	Date of Last Revision
Esthet•X® HD High Definition Micro Matrix Restorative	02/28/19
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
Light Curing Composite/Dental Filling Material	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

Hazardous Components	C.A.S. Number	Exposure Limits	%
Hydrophobic Amorphous Fumed Silica	68611-44-9	10 mg/m ³	< than 5
Silica (Amorphous)	67762-90-7	3 mg/m^3	< than 5
Barium boron fluoro alumino silicate glass	65997-18-4	10 mg/m^3	< than 30
Barium boron alumino silicate glass	65997-17-3	10 mg/m^3	< than 50
Urethane modified Bis-GMA dimethacrylate	126646-17-1	Not Established	< than 10
Polymerizable dimethacrylate resins	24448-20-2/109-16-0	Not Established	< than 20

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 ₂ , 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.			

^{*} The titanium dioxide in this product is inextricably bound in a manner that no airborne exposure occurs during normal use and handling. Therefore, this product is not classified as a carcinogen.

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	Engineering Controls: Not 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 resistant	Not Applicable			
	to the product.				
Inhalation	Not Required	Not Applicable			
Body Protection	Protective work clothing	Not Applicable			

9. Physical and Chemical Characteristics

Appearance: Various shades of viscous paste.		Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: Very High Viscosity Lic	quid (Paste)	Melting Point: Not Applicable
Specific Gravity: 2.1 g/cm ³	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,	Severity (Mild,	Acute and Chronic Health Effect(s)	Target Organ(s)
Exposure	Signs and Symptoms	or Lifetime	Moderate,		
		Exposure	Severe)		
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single &	Moderate	Irritation or possible allergic response.	Not Applicable
		Repeated		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 swallowed	Not Applicable	Mild	Not Applicable	Not Applicable
	using clinically relevant quantities				
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 (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: <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

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.