

Compolite

Universal Bond

Description:

Darby Compolite Universal Bond self-etching adhesive combines all the components needed for etching, priming, and bonding into a single adhesive solution, thereby eliminating separate etching and priming steps of the bonding process. Darby Compolite Universal Bond adhesive can be used for the bonding of both direct and indirect restorations.

Indications For Use

Direct Applications

- Light-cured composite and compomer restorations
- Composite/ceramic/amalgam/metal repairs, cavity sealing for amalgam restorations
- Light-cured or dual-cured core build-ups

Indirect Applications

- Veneers, porcelain, composite, and metal-based inlays, onlays, crowns, bridges, endodontic posts
- Cavity sealing as a pretreatment for indirect restoration

Contraindications

1. Patients who have a history of severe allergic reactions to methacrylate resins.
2. Direct pulp capping.
3. In combination with a chemical-cure or dual-cure material when there is insufficient light-curing.
4. For products containing eugenol and desensitizers, refer to the original equipment manufacturer (OEM) labeling for device compatibility.

Instructions For Use

Direct Restorations

Bonding Composites/Compomers to Dentin/Enamel

1. Prepare cavity. Wash thoroughly with water spray and air dry (Do not desiccate).

Note: For optimal adhesion, always prep (bevel) all enamel and/or margins prior to application of Darby Compolite Universal Bond.

2. Bottle Delivery: Dispense 2-3 drops of Darby Compolite Universal Bond adhesive into a clean well. Replace cap immediately after dispensing.
3. Using the disposable applicator brush, apply a generous amount of Darby Compolite Universal Bond adhesive to the enamel/dentin surface. Scrub the surface with a brushing motion for 20 seconds.

4. Apply a second application of Darby Compolite Universal Bond adhesive with a brushing motion for 20 seconds.

5. Dry the adhesive with gentle air first and then medium air for at least 5 seconds with oil-free air.

6. Light cure for 10 seconds.*

7. Apply composite according to manufacturer's instructions for use.

Indirect Restorations

See indication-specific information in sections A-D below.

Veneers, crowns, bridges, inlays, onlays and metal-based restorations (used in conjunction with a luting cement)

1. Clean the preparation. Wash thoroughly with water spray and air dry (Do not desiccate).

2. Bottle Delivery: Dispense 2-3 drops of Darby Compolite Universal Bond adhesive into a clean well. Replace cap immediately after dispensing.

3. Using the disposable applicator brush, apply a generous amount of Darby Compolite Universal Bond adhesive to the enamel/dentin surface. Scrub the surface with a brushing motion for 20 seconds.

4. Apply a second application of Darby Compolite Universal Bond adhesive with a brushing motion for 20 seconds.

5. Dry the adhesive with gentle air first and then medium air for at least 5 seconds with oil-free air. Avoid pooling of adhesive before light curing – refer to sections B & C.

6. Light cure for 10 seconds.*

Important: For indirect applications, use either a self-cured or dual-cured resin cement whenever there is no or limited light accessibility. Darby Compolite Universal Bond adhesive is compatible with all self-cured or dual-cured resin cements.

Darby Compolite Universal Bond adhesive can be used to prime metal, ceramic, and composite substrates/restorations.

Indication Specifics for Indirect Restorations

A. Veneers – Apply luting cement to veneer, seat the veneer, and cure the cement according to manufacturer's instructions for use.

B. Crowns, bridges, inlays, onlays and metal-based restorations – Avoid pooling of adhesive before light curing. Following light curing of the adhesive, apply luting cement (see important note below for cement recommendation) to the restoration or prep, seat the restoration, and cure the cement according to manufacturer's instructions for use.

C. Ceramic/Porcelain Restorations – Sandblast the surface with 50µm alumina with a pressure of about 30psi (0.2 MPa) and etch the restoration with hydrofluoric acid for 1 minute. Apply a coat of Darby Compolite Universal Bond adhesive on the internal surface of the restoration, air thin with gentle air first and then strong air to avoid pooling of the adhesive, and light-cure for 10 seconds* (light-curing of the Darby Compolite Universal Bond adhesive is optional if a dual-cure resin cement is used for cementation).

D. Metal-based, Zirconia-based, Alumina-based and Composite Restorations – Sandblast the internal surface with 50µm alumina with a pressure of about 60psi (0.4 MPa) for metal-based, zirconia-based and alumina-based restorations, or a pressure of about 15psi (0.1 MPa) for composite restorations. Apply a coat of Darby Compolite Universal Bond adhesive on the internal surface of the restoration, air thin with gentle air first and then strong air to avoid pooling of the adhesive, and light-cure for 10 seconds* (light-curing of the adhesive is optional if a dual-cure resin cement is used for cementation).

Important: Use either a self-cured or dual-cured resin cement whenever there is no or limited light accessibility (e.g. metal-based, zirconia-based, and alumina-based substrates). When there is good light-accessibility, use any dual-cure permanent cement.

E. Post Bonding – Apply adhesive on post and prep. Avoid pooling of the adhesive before light-curing. Remove excess adhesive with a dry applicator brush or absorbent paper point. Following light curing of the adhesive, apply any dual-cure resin cement onto the post, seat the post, and vibrate the post slightly avoiding the possibility of trapped air then cure according to the manufacturer's instructions.

F. Core Bonding – Apply core material according to manufacturer's instructions for use.

G. Recommended External Energy Source – ≥ 400 mW/cm² Wavelength (nm) for Curing: 400-500 nm

Note: Use a light-cured or dual-cured core material. Always light-cure in incremental build-up of core material. Refrigerate upon receipt between 2°-8° C.

*Always follow light manufacturer's recommendation for cure times for each product type.

CAUTION

1. Darby Compolite Universal Bond adhesive bottle should be tightly closed immediately after use.
2. Corrosive Liquid: Avoid contact with skin, eyes and soft tissue. In case of contact with skin or eyes, flush immediately and thoroughly with water. Get medical attention for eyes. Do not take internally.
3. Uncured methacrylate resin may cause contact dermatitis.
4. Darby Compolite Universal Bond adhesive is a light-cured material. Once the material is placed in a mixing well, use immediately or protect from ambient light.
5. Darby Compolite Universal Bond adhesive contains acetone and is flammable. Keep away from sources of ignition.

CAUTION: Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes, and soft tissue. Wash thoroughly with water after contact.






To reorder, Call 800.645.2310 or visit darby.com
 Distributed by: Darby Dental Supply, LLC,
 Jericho, NY 11753

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SAFETY DATA SHEET (SDS)

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION			
Product Identifier: Darby Compolite Universal Bond		Recommended Use: Dental Bonding Agent	
Product Identifier: Darby Dental Supply LLC 300 Jericho Boulevard, Jericho, NY 11753 Phone: 800.645.2310		Emergency Telephone Number: Chemical Spills, Leaks, 800.645.2310 Fire, Exposure or Accident: Only CH2MTRC 1-800-424-9300 (in the US) 1-703-527-3887 (outside the US)	
SECTION 2 - HAZARD(S) IDENTIFICATION			
GHS Hazard Classification of the Substance or Mixture: Flammable Liquids Category 2 Skin Irritation Category 2 Eye Irritation Category 2A Skin Sensitizer Category 1 Specific Target Organ Toxicity Single Exposure Category 3 Specific Target Organ Toxicity Repeated Exposure Category 2			
Label Elements: Danger!		Hazard Phrases: Highly flammable liquid and vapor. Causes serious eye irritation. Causes skin irritation. May cause drowsiness and dizziness. May cause damage to organs through prolonged or repeated exposure.	
Precautionary Phrases: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.			
Do not breathe vapor. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Take off contaminated clothing. Rinse skin with water/shower. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER. If you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Store in a well-ventilated place. Keep Cool. Store locked up. Dispose of contents and container in accordance with local and national regulations.			
NFPA Ratings (0-4)		NFPA Ratings (0-4)	
Health = 0 Flame = 0 Reactivity = 0		Health = 0 Flame = 0 Reactivity = 0	
SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS			
Chemical Name, Common Name and Synonyms:		CAS # and other unique identifiers	
Acetone		67-64-1 30-60	
2-Hydroxyethyl methacrylate		868-77-9 5-10	
Ethanol		67-17-5 5-10	
2-Hydroxy-1, 3-propanediyl bis(methacrylate)		1830-78-0 1-5	
SECTION 4 - FIRST-AID MEASURES			
Inhalation: Immediately remove victim to fresh air. Get immediate medical attention.			
Skin Contact: Flush thoroughly with water. Get medical attention if irritation or symptoms of severe develop. Remove and launder contaminated clothing before re-use.			
Eye Contact: Rinse thoroughly with water. Get medical attention if irritation occurs and persists.			
Ingestion: Do NOT induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. Keep the victim calm and warm. Get immediate medical attention.			
Most important symptoms and effects, acute and delayed: Causes serious eye irritation and skin irritation. Prolonged contact can cause defatting to the skin. If inhaled, can cause central nervous system depression and may cause drowsiness and dizziness. Ingestion can be irritating to mouth, throat and stomach.			
Indication of immediate medical attention and special treatment, if needed: None required under normal conditions of use.			
SECTION 5 - FIRE-FIGHTING MEASURES			
Suitable (and Unsuitable) Extinguishing Media: Use any media appropriate for the surrounding fire. Cool fire exposed containers with water.			
Specific Hazards Arising from the Chemical: Combustion may produce carbon dioxide, carbon monoxide, phosphorus oxides, and metal oxides.			
Special Protective Equipment and Precautions for Firefighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for fires in areas where chemicals are used or stored. Cool fire-exposed containers with water. Contains water used in firefighting from entering sewers or natural waterways.			
SECTION 6 - ACCIDENTAL RELEASE MEASURES			
Personal precautions, protective equipment, and Emergency procedures: Evacuate spill area and keep unexposed personnel away. Avoid contact with eyes, skin, and clothing. Wear appropriate protective clothing and equipment.			
Environmental Precautions: Avoid releases to the environment. Report spill as required by local and federal regulations.			
Methods and Materials for Containment and Cleaning Up: Prompt clean-up and removal are necessary. Absorb spills with an inert material and place in an appropriate waste disposal container.			
SECTION 7 - HANDLING AND STORAGE			
Precautions for Safe Handling: Prevent contact with eyes, skin and clothing. Always wear impervious gloves, chemical safety goggles and protective clothing when handling this material. Wash thoroughly with soap and water after handling. Do not eat, drink or smoke in the work area. Do not breathe dust or vapors. Use with adequate ventilation. Remove and wash contaminated clothing before reuse. Empty containers retain product residues which can be hazardous. Follow all SDS precautions when handling empty containers.			
Conditions for Safe Storage, Including any Incompatibilities: Store in a cool, dry, well-ventilated area away from direct sunlight. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.			
SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION			
Chemical		Exposure Limit	
Acetone		67-64-1	
2-Hydroxyethyl methacrylate		868-77-9	
Ethanol		67-17-5	
2-Hydroxy-1, 3-propanediyl bis(methacrylate)		1830-78-0	
Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.			
Respiratory Protection: None under normal use conditions with adequate ventilation. For operations where the occupational exposure limits are exceeded, an approved respirator with particulate cartridges is recommended. Equipment selection depends on contaminant type and concentration. Select in accordance with applicable regulations and good industrial hygiene practice. For firefighting, use self-contained breathing apparatus.			
Hand Protection: Impervious gloves are suggested to prevent skin contact. Contact your glove supplier for selection assistance.			
Skin Protection: Wear protective clothing as needed to avoid skin contact and contamination of personal clothing.			
Eye Protection: Chemical safety goggles are recommended if contact is possible.			

7.5"

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES				
Appearance:	Light yellow liquid	Odor:	Fruity/Keitone	
Color Threshold:	Not available	pH:	Not available	
Melting/Freezing Point:	Not available	Boiling Point/Range:	Not available	
Flash Point:	<12.78°C (<55°F)	Evaporation Rate:	Not available	
Flammability (Solid, Gas):	Not applicable	Flammability Limits:	LEL: Not applicable UEL: Not applicable	
Vapor Pressure:	Not available	Vapor Density:	Not available	
Relative Density:	Not available	Solubilities:	Partially soluble in water	
Partition Coefficient: (N-Octanol/Water):	Not available	Autofluorescence Temperature:	Not available	
Decomposition Temperature:	Not available	Viscosity:	Not available	
SECTION 10 - STABILITY AND REACTIVITY				
Reactivity: The product is not expected to be reactive. Chemical Stability: Stable under normal storage and handling conditions. Possibility of Hazardous Reactions: Hazardous polymerization will not occur. Conditions to avoid: Avoid heat and all possible sources of ignition (spark or flame). Incompatible Materials: Oxidizing materials. Hazardous decomposition products: None if stored normally.				
SECTION 11 - TOXICOLOGICAL INFORMATION				
Potential Health Effects: Inhalation: Can cause central nervous system depression. May cause drowsiness and dizziness. Skin Contact: Causes skin irritation. Defatting to the skin. Eye Contact: Causes serious eye irritation. Ingestion: Irritating to mouth, throat, and stomach. Swallowing can cause central nervous system depression. Chronic Hazards: May cause damage to organs through prolonged or repeated exposure. Prolonged or repeated contact can defat the skin and lead to irritation, cracking, and dermatitis. Skin Sensitization: No adverse effects expected. Components are not sensitizers. Respiratory Sensitization: No data available. This product is not expected to cause respiratory sensitization. Germ Cell Mutagenicity: Mercury: Mutagenic effects have been observed with humans. Carcinogens: None of the other components are listed as a carcinogen or potential carcinogen by IARC, NTP, ACGIH, or OSHA. Development / Reproductive Toxicity: Mercury: Reproductive effects have been observed on tests with laboratory animals. Specific Target Organ Toxicity (Single Exposure): Single exposure to acetone and ethanol may cause narcotic effects. Single exposure to 2-hydroxyethyl methacrylate, ethanol, and 2-hydroxy-1, 3-propanediyl bis(methacrylate) may cause respiratory tract irritation. Specific Target Organ Toxicity (Repeated Exposure): Repeated exposure to ethanol may affect the liver. Aspiration Toxicity: Not an aspiration hazard.				
Acute Toxicity Values: Protect ATE: 21372.9 mg/kg (Oral), Acetone: LC50 Inhalation rat: 76 mg/L/4hr, LD50 Dermal rabbit: 20000 mg/kg, LD50 Oral rat: 5800 mg/kg, 2-Hydroxyethyl methacrylate: LD50 Oral rat: 4200 mg/kg, LD50 Dermal rabbit: ~3000 mg/kg Ethanol: LC50 Inhalation rat: 124.7 mg/L/4hr, LD50 Oral rat: 7050 mg/kg, LD50 Dermal rabbit: >20000 mg/m ²				
SECTION 12 - ECOLOGICAL INFORMATION				
Toxicity: Acetone: 96 hr LC50 Pimephales promelas: 100 mg/L, 96 hr EC50 Algae: 20.565 mg/L, 48 hr LC50 Crustaceans: 6000 mg/L, 48 hr LC50 Daphnia magna: 10 mg/L, 2-Hydroxyethyl methacrylate: 96 hr LC50 Pimephales promelas 227 mg/L, Ethanol: 96 hr LC50 Pimephales promelas 13500 mg/L, 48 hr EC50 Daphnia magna 2000 µg/L, 48 hr LC50 Crustaceans 25500 µg/L. Persistence and Degradability: Product is readily biodegradable. Bioaccumulative Potential: Acetone has a BCF of 0.69, log Pow -0.27, potential for bioaccumulation is low. 2-Hydroxyethyl methacrylate has a BCF of 1.3 - 1.5, log Pow 0.42, potential for bioaccumulation is low. Ethanol: log Pow 0.35, potential for bioaccumulation is low. Mobility in Soil: No data available. Other Adverse Effects: No data available.				
SECTION 13 - DISPOSAL CONSIDERATIONS				
Disposal: For unused product, dispose of in accordance with Federal and local regulations. Container Disposal: Dispose of empty container in accordance with Federal and local regulations.				
SECTION 14 - TRANSPORT INFORMATION				
	UN Number	UN Proper Shipping Name	Hazard Classes	Packing Group
US DOT	UN1993	Flammable liquids, n.o.s. (acetone, ethanol) (3)	3	II
EU AD/RID	UN1993	Flammable liquids, n.o.s. (acetone, ethanol)	3	II
IMDG	UN1993	Flammable liquids, n.o.s. (acetone, ethanol)	3	II
IATA/ICAO	UN1993	Flammable liquids, n.o.s. (acetone, ethanol) (3)	3	II
Special Precautions for User: Transport with user's premises: Always transport in closed containers that are upright and secure. Ensure that person transporting the product know what to do in the event of an accident or spillage. Transport in Bulk According to Annex II, MARPOL 73/78 and the IBC Code: Not applicable as a product is transported only as packaged form.				
SECTION 15 - REGULATORY INFORMATION				
U.S. Federal Regulations: EPA SARA 311/312 Hazard Classification: Refer to Section 2 for OSHA Hazard Classification. EPA SARA 313: This Product Contains the Following Chemicals Subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None. Protection of Stratospheric Ozone: This product is not known to contain or to have been manufactured with ozone depleting substances as defined in 40 CFR Part 82, Appendix A to Subpart A. CERCLA SECTION 103: This product is not subject to CERCLA reporting requirements, however, many states have more stringent reporting requirements. Report spills required under federal, state and local regulations. International Inventories: US EPA TSCA Inventory: All of the components of this product are listed on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory or exempt. Canada CEPA: All of the components of this material are listed on the DSL or exempt.				
SECTION 16 - OTHER INFORMATION				
Abbreviations and Acronyms: None. Other Information Not Contained Elsewhere: None.				



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4.3"

Folding line