

INSTRUCTIONS FOR USE

PARKELL PRODUCT INFORMATION

ABSOLUTE DENTIN™

CAUTION: Rx only

STORE IN REFRIGERATOR. AVOID FREEZING.

KITS AND REFILLS AVAILABLE:

	1- 50 ml/110 gm cartridge (fits DS-50, 1:1 / 2:1 automix gun) <u>Total material provided is 50 ml/110 gm</u>	2 - 10 ml/22 gm cartridges (fit 10 ml, 1:1 automix gun) <u>Total material provided is 20 ml/44 gm</u>
Tooth Shade	Stock No. S301	Stock No. S305
Arctic White Shade	Stock No. S300	Stock No. S304
Blue Shade	Stock No. S307	Stock No. S306
Mixing tip refills	Stock No. S302 (yellow)	Stock No. S328 (brown)
Intraoral tip refills	Stock No. S308 (Dark Grey)	Stock No. S329 (for brown)
Dispensing Gun	Stock No. S343 (1:1 / 2:1 for 50ml cartridge)	Stock No. S327 (1:1 for 10ml cartridge)

DESCRIPTION:

Parkell's ABSOLUTE DENTIN™ is a strong, dual-cure, composite resin material that is highly filled with fluoridated barium/aluminum glass for radiopacity. It is intended for core fabrication, and is supplied in two convenient packages: a 50 ml/110 gm cartridge and a 10 ml/22 gm cartridge, each to be expressed with the appropriate automix gun. The uncured material flows well and stacks without slumping, while the cured material "feels" much like dentin when prepared with rotary instruments.

ABSOLUTE DENTIN works with all dentin/enamel bonding agents that are compatible with dual-cure or self-cure composites, including all of Parkell's 4-META-based bonding products (Brush&Bond™, Touch&Bond®, Amalgambond™, C&B Metabond® and SSecure™). It is also compatible with Parkell's Add&Bond™, DuraFinish™ and DuraFinish™ All-Cure.

ABSOLUTE DENTIN kits are available in three shades: Tooth Shade (similar to A2/A3), Arctic White (A1/B1), and Blue (easily distinguished from surrounding tooth structure). Each kit contains an appropriate number of mixing tips and intraoral tips.

DIRECTIONS:

- 1) Apply the appropriate dentin/enamel bonding agent to the prepared tooth, following the material's instructions. Since ABSOLUTE DENTIN is a dual-cure material, make sure that the bonding agent chosen is compatible with DUAL-CURE or SELF-CURE composites. Certain non-Parkell self-etching bonding agents may interfere with the setting ability of dual-cure composites, so check the instructions for your bonding agent before proceeding.
- 2) Setting up the product for use:
 - a. If using the 50 ml automix cartridge, insert it into any DS-50 (1:1 / 2:1) impression gun such as Parkell's Stock No. S343. **Remove and discard the blue sealing cap or used mixing tip from the cartridge, and express out a small amount of material through both round orifices.** Then attach a yellow mixing tip to the cartridge, and a yellow intraoral tip to the mixing tip. You may want to cut off the last 1 mm of the intraoral tip to give you better flow volume.
 - b. If using the 10 ml automix cartridge, insert it into the appropriate 10 ml (1:1) impression gun such as Parkell's Stock No. S327. Remove and discard the brown sealing cap or used mixing tip from the cartridge, and express out a small amount of material through both round orifices. Then attach a brown mixing tip to the cartridge, and a clear, angled intraoral tip to the mixing tip.
- 3) Express out a pea-sized amount of ABSOLUTE DENTIN through the tip onto a pad to ensure a complete mix of base and catalyst pastes. Immediately express the mixed material

directly from the cartridge onto the bonding agent coated tooth. A matrix band or core-forming capsule may be used to contain the material.

- 4) ABSOLUTE DENTIN will self-cure without light in about 4 minutes. The light initiator in the product is camphorquinone (CQ), which has an activation range of between 460 and 480 nm. ABSOLUTE DENTIN will light-cure to a depth of 3 mm with a 40 second exposure to any dental curing light producing an intensity of at least 400 mW/cm². Actual clinical depth of cure will depend on factors such as time, light intensity, device condition, distance between the light and the restoration, and material shade.
- 5) Once fully cured, prepare the core as usual with rotary instruments of choice.
- 6) Leave the used mixing tip in place on the cartridge to serve as the sealing cap between uses. The cartridge, used mixing tip and gun may be disinfected with appropriate dental surface disinfectants. Check with the disinfectant manufacturer before use.

STORAGE AND USE:

Store the material in a cool, dry place. For longest shelf life, refrigeration without freezing is preferred. After removal from the fridge, allow ABSOLUTE DENTIN to warm to room temperature for best handling. Cold material may be difficult to express and take longer to cure.

CONTRAINDICATIONS:

ABSOLUTE DENTIN should not be used on or by persons who are methacrylate sensitive. Uncured material should not be swallowed.

WARRANTY

Parkell will replace defective material. **This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described. Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.

Parkell's Quality System is certified to ISO 13485 and ISO 9001.

EC|REP

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SEE OTHER SIDE
FOR MSDS SHEET

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PARKELL, INC.
 Company Telephone Number: (631) 249-1134
 300 Executive Drive
 Edgewood, NY 11717
 24-Hour Emergency Phone: InfoTrac 1-800-535-5053

PRODUCT NAME: ABSOLUTE DENTIN™ (All Shades) **MSDS NO: S300, etc.**

SECTION 2 - COMPOSITION INFORMATION ON INGREDIENTS

HAZARDOUS COMPONENTS	CAS NUMBER	PEL N/E	ILV N/E	%
Uncured Methacrylate Ester Monomers	N/A	N/E	N/E	
Benzoyl Peroxide	94-36-0	5 mg/m ³	5 mg/m ³	
Other ingredients:				
Silane treated glass fillers, initiators and stabilizers				

SECTION 3 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:
POTENTIAL HEALTH EFFECTS
EYES: May cause irritation and damage if not removed promptly.
SKIN: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals. Prolonged or excessive inhalation may cause respiratory tract irritation.
INHALATION: May be harmful if swallowed. Seek medical attention.
CHRONIC EFFECTS: SIGNS & SYMPTOMS:
CARCINOGENICITY: No NTP? No IARC MONOGRAPHS? No OSHA?

SECTION 4 - FIRST-AID MEASURES

EYES: Flush with plenty of water. Contact physician.
SKIN: Wash with soap and water.
INHALATION: Remove to fresh air. If irritation persists, contact physician.
INGESTION: Contact a physician immediately.
NOTE TO PHYSICIANS:

SECTION 5 - FIRE-FIGHTING MEASURES

FLASH POINT (TCC): N/D **FLAMMABLE LIMIT (air, % by vol):** UPPER N/D LOWER: N/D
FLAMMABILITY CLASSIFICATION (CFR 1910.1200):
EXTINGUISHING MEDIA: Chemical Foam, CO₂, Dry Chemical
FIRE FIGHTING INSTRUCTIONS: Wear Self Contained Breathing Apparatus.
UNUSUAL FIRE & EXPLOSION HAZARDS: Heat can cause polymerization with rapid release of energy.
HAZARDOUS COMBUSTION PRODUCTS:

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Absorb spills with inert material; keep spilled material in closed containers and dispose of as recommended. Avoid skin contact. Wear protective equipment.

SECTION 7 - HANDLING AND STORAGE

HANDLING: Avoid skin contact. Wear protective equipment
STORAGE: Store in a cool, dry place away from heat, sunlight, oxidizing, reducing agents and ignition sources.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: Adequate ventilation to maintain PEL.
EYE/FACE PROTECTION: Safety glasses or goggles.
SKIN PROTECTION: Gloves - latex or other impervious rubber material.
RESPIRATORY PROTECTION: Use in a well ventilated area.
EXPOSURE GUIDELINES:

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR: N/D Colored paste with mild fruity ester-like odor.
BOILING POINT: N/D **SPECIFIC GRAVITY (H₂O = 1):** 2.0
VAPOR PRESSURE: Not Determined **PERCENT VOLATILES:**
VAPOR DENSITY (Air = 1): Not Determined **EVAPORATION RATE (Butyl Acetate = 1):**
SOLUBILITY IN WATER: Insoluble **pH:**

SECTION 10 - STABILITY AND REACTIVITY

STABILITY: Stable if stored as directed **HAZARDOUS POLYMERIZATION:** Will not occur when using clinical amounts of this material
CONDITIONS TO AVOID: Heat, sunlight, aging and contamination
INCOMPATIBILITY (Materials to avoid): Oxidizing agents, reducing agents, peroxides and free radical initiators.
HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of carbon.

SECTION 11 - TOXICOLOGICAL INFORMATION

SECTION 12 - ECOLOGICAL INFORMATION

SECTION 13 - DISPOSABLE CONSIDERATIONS

Unpolymerized (uncured) material may be RCRA hazardous waste. Waste must be disposed of in accordance with federal, state, and local environmental control regulations.

SECTION 14 - TRANSPORT INFORMATION (not meant to be all-inclusive)

PROPER SHIPPING NAME: N/A **UN/NA NUMBER:**

SECTION 15 - REGULATORY INFORMATION (not meant to be all-inclusive)

SECTION 16 - OTHER INFORMATION

HMS CODES: HEALTH - 2 **FLAMMABILITY - 1** **REACTIVITY - 2**
WORK/HYGIENIC PRACTICES: Handle in accordance with good personal hygiene and safety practices. These practices include: avoid unnecessary exposure and wash hands before eating, drinking or smoking.

DATE PREPARED: 01/22/14 **PREPARED BY:** R. Burke
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