ACCOLADE OP MASK MATERIAL SAFETY DATA SHEET

SECTION XI: TOXICOLOGICAL INFORMATION

No evidence of carcinogenicity.

SECTION XII: ECOLOGICAL INFORMATION

Waste may be considered as inert material.

SECTION XIII: DISPOSAL CONSIDERATIONS

Dispose of safely in accordance with local, state, and federal regulations.

SECTION XIV: TRANSPORT INFORMATION

Stable under normal conditions of use, transportation, and storage.

SECTION XV: REGULATORY INFORMATION

510k #: K020760

SECTION XVI: OTHER INFORMATION

None

The data and information given in this material safety data sheet are accurate to the best of our knowledge on the date of preparation. It does not indicate any warranty or representation.

LIMITATION OF LIABILITY

Except where prohibited by law, Danville Materials will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.



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DANVILLE FLOWABLE COMPOSITE Accolade OP MASK

Accolate OP Mask is a light-cure paintable composite used as a first increment for masking tooth discolorations and metals. Accolade OP Mask is built on Accolade chemistry and requires no mixing. It can be used between a bonded tooth surface and an overlaid resin-based restorative or porcelain veneer to mask unwanted color, for example tetracycline stain. It can be used on prepared metals to mask the metal color for repair of porcelain fused to metal crowns.

Accolade OP Mask is classified as a microhybrid, having average filler size of 0.7 microns. The filler content is 50% by weight. Danville is not aware of any incompatibilities between Accolade OP Mask and other composites or adhesives.

INSTRUCTIONS FOR USE

- Isolate tooth with a rubber dam or use Danville's Dam Cool[™] light-cured dental dam.
- 2. Preparing the surface for Accolade OP Mask:
 - a. Tooth structure masking: Complete tooth surface preparation with conventional means or with an air abrasive device such as Danville's PrepStart™. Apply a bonding agent such as Danville's Prelude™ per manufacturer's instructions.
 - b. Fractured porcelain repair: Metal and porcelain surfaces can be prepared using alumina air abrasion from Danville's MicroEtcher[™] followed by appropriate metal and porcelain primers according to their manufacturer's instructions for use. Alternatively, SilJet[™] may be applied to the fractured porcelain and metal surfaces using a Microetcher followed by a silane primer such as Danville's S-Bond™.
- Preparing Accolade OP Mask for use: Remove cap and set aside. Twist to lock on a new needle tip; for Accolade OP Mask use a 25-gauge tip. When finished dispensing material, remove tip and discard. Replace original cap to preserve product and avoid cross contamination. Syringe can be disinfected by wiping with any standard dental office disinfectant. Handpiece barrier plastic sleeves may provide greater prevention of cross-contamination. Insert syringe with new needle tip into barrier sleeve, piercing only the needle through the plastic. Avoid cross-contamination between patients by avoiding resin suck-back.
- Float Accolade OP Mask directly onto prepared surface, using the tip of the needle to direct it 4. over the surface being masked. Tooth Shade will provide an esthetic result in most cases. Use only enough Accolade OP Mask as is needed to block the unwanted color. White Shade and Tooth Shade Accolade OP Mask can be combined directly on the preparation surface to obtain a lighter shade which may be desirable in some cases.
- 5. Light-cure the Accolade OP Mask layer for 30 seconds or more with a halogen curing light (assuming a light output of 600 mW/cm²). Other light sources or intensities require an adjustment to the cure time. See curing light manufacturer's instructions.
- Apply a resin bond such as Danville's E-Bond[™] to the Accolade OP Mask layer and cure per 6. manufacturer's instructions prior to use of a highly filled composite. Alternately, apply flowable composite such as Danville's StarFlow[™] and cure per manufacturer's instructions.

STORAGE

Best if stored below 75° F (24° C). Conditions to avoid: Prolonged extreme heat beyond 40°C.

ADDITIONAL NOTES

- Do not contact the composite with materials containing eugenol. Eugenol can impair the polymerization of the composite and cause discoloration.
- Contact of resin-based composites with skin should be avoided, especially by anyone having known resin allergies.

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SECTION I: IDENTIFICATION

Company Name: Danville Materials 3420 Fostoria Way Suite A-200 San Ramon, CA 94583

Phone (800) 827-7940 Fax: (925) 973-0764 Prepared: September 26, 2011

SECTION II: HAZARD(S) IDENTIFICATION

OSHA Permissible Exposure Limits: None Other Exposure Limit Used: None ACGIH Threshold Exposure Limit: None Chronic, Other: None Acute Overexposure: Irritation to eyes and skin may occur with uncured resins. May cause skin sensitivity in select individuals. Medical Conditions generally aggravated by exposure: None known Hygienic Practices: None Primary Route(s) of Exposure: Skin: Yes. Inhalation and ingestion: No

SECTION III: COMPOSITION/INFORMATION ON INGREDIENTS

Barium Glass BIS GMA Amorphous Silica

SECTION IV: FIRST-AID MEASURES

Signs of Exposure: Severe skin or eye irritation, redness or burning sensation. Skin: Wash off affected area with soap and water. Ingestion: Seek immediate medical advice, carry container with label.

Eyes: Rinse immediately with plenty of water and seek medical advice.

SECTION V: FIRE-FIGHTING MEASURES

Flash Point: > + 104 deg. F Extinguishing Media: Carbon Dioxide, foam, dry chemical Special Fire-Fighting Procedures: None Flammable Limits: ND Unusual Fire and Explosion Hazards: None

SECTION VI: ACCIDENTAL RELEASE MEASURES

None

SECTION VII: HANDLING AND STORAGE

Spill Management: Use absorbent to collect the material. Wash contaminated surfaces with soap and water.

SECTION VIII: EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory: None Eye Protection: Safety goggles Gloves: Surgical rubber/PVC gloves Other Clothing & Equipment: Face Mask Ventilation: None required, local exhaust recommended

SECTION IX: PHYSICAL AND CHEMICAL PROPERTIES

(ND) = Not Determined NA = Not Applicable Vapor Pressure mm HG: ND Evaporation Rate (Ether = 1): NA Solubility in H20: Insoluble Appearance: Tooth-Shaded Resin Paste Specific Gravity (H2 = 1): > 1

SECTION X: STABILITY AND REACTIVITY

Stability: Unstable () Stable (X) Conditions to avoid: Prolonged extreme heat beyond 40 deg. C, and intense light. Incompatibility: ND Hazardous Decomposition Products: None known Hazardous Polymerization: May occur () Will not occur (X) None