

SAFETY DATA SHEETS

This SDS packet was issued with item:

072343325

N/A

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

Vapor Pressure mm HG: NA
Evaporation Rate (Ether = 1): NA
Solubility in Water: Soluble
Appearance: Blue Gel

Vapor Density (Air = 1): NA
% Volatile by Volume: NA
Boiling Point: NA
Odor: None

SECTION X - STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Prolonged extreme heat
Incompatibility: (Materials to avoid) Contact with metals
Hazardous Decomposition Products: None
Hazardous Polymerization: None

SECTION XI - TOXICOLOGICAL INFORMATION

None

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 #: K092912

SECTION XVI - OTHER INFORMATION

None

The data and information given in this MSDS are accurate on the date of preparation. It does not indicate any warranty or representation. We disclaim all liability relating to use of this material since this is beyond our control.



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90393 REV F



A dentin shaded, radiopaque, fluoride releasing, dual cured, strong, flowable, microhybrid composite.

INSTRUCTIONS

StarFill 2B™ was specifically developed for the directed shrinkage technique of posterior composite placement, first described by Dr. Raymond Bertolotti. StarFill 2B™ is also ideal for luting posts, core buildups, crowns, veneers and any application where light transmission is in question. Being a dual cure, StarFill 2B™ can be rapidly cured with a light. Starfill 2B™ contains 61% filler by weight (41% by volume).

MIXING INSTRUCTIONS

A. Automix Syringe (one double barrel)

1. Remove twist off cap and attach automix tip.
2. Depress plunger with smooth, even pressure until no air is left in mix tip.
3. Syringe StarFill 2B™ directly into restoration.
4. Do not remove the automix tip after use. The used tip serves as a convenient seal until the next use.

B. Base & Catalyst Syringes (individual)

1. Hand mix equal portions of the StarFill 2B™ Base and Catalyst.
2. Place StarFill 2B™ using a Centrix needle tip or similar syringe tip.
3. The tips and silicone caps are color coded. It is suggested that white caps be used on white tips and black caps be used on black tips to prevent cross-contamination of base and catalyst.

USE INSTRUCTIONS

Directed Shrinkage Technique for Posterior Composites

StarFill 2B™ is ideal for the "Directed Shrinkage" technique^{1,2,3} for composite placement.

1. Cut conservative prep. Use of Danville's CariesFinder™ or other caries detection dye as a guide is suggested.
2. Etch enamel and dentin for 15 to 30 seconds with a liquid phosphoric acid etchant such as SureEtch™.
3. A highly recommended optional step to reduce sensitivity is to apply Danville's MicroPrime™ desensitising agent for 20 seconds (minimum) penetration time. (Note:

¹Bertolotti R.L. *PP&A Aesthetic Chronicle* 1991; 3, 53-58.
²Ferrari M. *PP&A Aesthetic Chronicle* 1993; 5, 29-36.
³Garberoglio R. et al. *Am J Dent* 1995; 8, 303-307.

Do not use MicroPrime™ with self etch primers.)

4. Apply bonding agent and cure.
5. Apply StarFill 2B™ and allow to self cure for at least 2 1/2 minutes. (To achieve directed shrinkage effect, the minimum depth is a Dycal-like layer which includes the gingival margin.) (Note: StarFill 2B™ can be light cured for faster set but that cure negates the directed shrinkage effect.)
- 6a. Place a light cure posterior composite and cure. (There is no need for bonding agent between the StarFill 2B™ and the overlying composite.

OR

- 6b. A bite form technique, using a sectional matrix system such as Contact Matrix, may be used to form the composite. Place the composite, remove the Contact Ring, apply glycerine gel on the occlusal and have the patient bite into centric occlusion. Cure the composite while the patient's mouth is closed. Have the patient open and cure again.
7. Remove the matrix.
8. Finish and polish.
9. Avoid cross-contamination between patients by replacing mixing tip between patients. Disposable handpiece or syringe plastic barrier sleeves may provide greater prevention of cross-contamination. Insert StarFill 2B™ automix syringe with new tip into barrier sleeve, piercing only the automix tip through the plastic. If used with Centrix tip, follow Centrix directions for use.

STORAGE

Refrigerate for full shelf life. Use at room temperature.

ADDITIONAL NOTES

- Do not store the composite material in proximity to eugenol-containing products, nor let the composite come into contact with materials containing eugenol. Eugenol can impair the hardening of the composite and cause discoloration.
- Contact of resin pastes with skin should be avoided, especially by anyone having known resin allergies.

MATERIAL SAFETY DATA SHEET

SECTION I - PRODUCT IDENTIFICATION

Company: Danville Materials
3420 Fostoria Way Ste A-200
San Ramon, CA 94583
Phone: (800) 827-7940
Fax: (925) 973-0764
Prepared: January 14, 2013

SECTION II - HAZARD(S) IDENTIFICATION

Chronic, Other: None
Acute Overexposure: Irritation to eyes and skin
Medical Conditions Generally Aggravated by Exposure: None Known
Hygienic Practices: Use good personal hygiene
Primary Route(s) of Exposure: Skin, eye, ingestion

SECTION III - COMPOSITION/INFORMATION ON INGREDIENTS

| Material | CAS | % WGT | OSHA PEL | ACGIH TLV |
|------------------|-----------|-------|----------|-----------|
| Barium Glass | | 45-65 | 15 | 10 |
| BIS GMA | | 15-45 | N/L | N/L |
| Glycerin | 56-81-5 | | ND | 10mg/m3 |
| Silica/Amorphous | 7631-86-9 | | ND | 0.1mg/m3 |
| Blue Food Dye | ND | | | |

(ND = Not Determined NA = Not Applicable NL = Not Listed)

SECTION IV - EMERGENCY AND FIRST AID PROCEDURES

Skin: Wash off affected area with soap and water.
Ingestion: None, essentially non-toxic orally
Eyes: Rinse immediately with plenty of water and seek medical advice.

SECTION V - FIRE-FIGHTING MEASURES

Flash Point: >+104°C
Extinguishing Media: Carbon Dioxide, Foam, Dry Chemical
Special Fire Fighting Procedures: None
Flammable Limits: NA
Unusual Fire and Explosion Hazards: None

SECTION VI - ACCIDENTAL RELEASE MEASURES

None

SECTION VII - SAFE HANDLING AND USE PRECAUTIONS

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

SECTION VIII - PROTECTION INFORMATION/CONTROL MEASURES

Respiratory: None required
Eye Protection: Safety goggles
Glove: Surgical rubber/PVC gloves
Other Clothing & Equipment: none
Ventilation: None required

StartFill 2B™

SECTION 1 : Identification of the substance/mixture and of the supplier

Product name: StartFill 2B™

Manufacturer/Supplier Trade name:

Manufacturer/Supplier Article number: 90393

Recommended uses of the product and restrictions on use:

Manufacturer Details:

Danville Materials
3420 Fostoria Way Suite a200
San Ramon, CA 94583

Supplier Details:

Danville Materials
3420 Fostoria Way Suite a200
San Ramon, CA 94583

Emergency telephone number:

ChemTrec Inc 1-800-424-9300,703-527-3887 (CHEMTREC)

SECTION 2 : Hazards identification

Classification of the substance or mixture:



Irritant

Skin irritation, category 2
Eye irritation, category 2A
Skin sensitization, category 1

Skin sensitization - Category 1.

Skin irritation - Category 2.

Eye Irritation - Category 2.

Signal word: Warning

Hazard statements:

Causes skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

Precautionary statements:

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read label before use. Wash skin thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace. Specific treatment (see supplemental first aid instructions on this label).

IF ON SKIN: Wash with soap and water.

Take off contaminated clothing and wash before reuse.

If skin irritation or a rash occurs: Get medical advice/attention.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do.

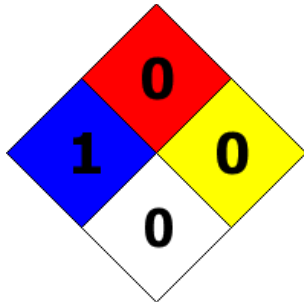
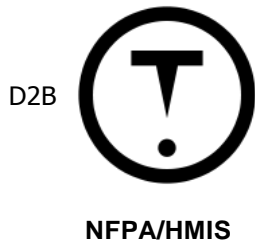
Continue rinsing.

If eye irritation persists get medical advice/attention. Dispose of contents and container as instructed in Section 13.

Other Non-GHS Classification:

WHMIS

StartFill 2B™



NFPA SCALE (0-4)

| | |
|----------------------------|----------|
| Health | 1 |
| Flammability | 0 |
| Physical Hazard | 0 |
| Personal Protection | X |

HMIS RATINGS (0-4)

SECTION 3 : Composition/information on ingredients

| Ingredients: | | |
|---------------------------|--|---------|
| CAS 7631-86-9 | Silica amorphous | <3 % |
| CAS 1565-94-2 | Bisphenol A-Glycidyl Methacrylate (BIS GMA) | 15-45 % |
| CAS 13255-26-0 | Barium Glass | 45-65 % |
| CAS N/A | Non-hazardous filler material | 41 % |
| CAS 56-81-5 | Glycerin | <5 % |
| CAS N/A | Blue Food Dye | <1 % |
| Percentages are by weight | | |

SECTION 4 : First aid measures

Description of first aid measures

After inhalation: Move exposed to fresh air. Give artificial respiration if necessary. If breathing is difficult give oxygen. Loosen clothing and place exposed in a comfortable position. Seek medical assistance if cough or other symptoms appear.

After skin contact: Wash hands and exposed skin with soap and plenty of water. Seek medical attention if irritation persists or if concerned.

After eye contact: Protect unexposed eye. Flush exposed eye gently using water for 15-20 minutes. Remove contact lenses while rinsing. Keep eyelids open while rinsing. Seek medical attention.

After swallowing: Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Immediately seek medical attention.

Most important symptoms and effects, both acute and delayed:

Shortness of breath. Headache. Nausea. Dizziness. Severe skin or eye irritation, redness or burning sensation.
None identified.

Indication of any immediate medical attention and special treatment needed:

StartFill 2B™

If seeking medical attention provide SDS document to physician. Physician should treat symptomatically.

SECTION 5 : Firefighting measures

Extinguishing media

Suitable extinguishing agents: Use water, dry chemical, chemical foam, carbon dioxide, or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents: None identified.

Special hazards arising from the substance or mixture:

Thermal decomposition can lead to release of acrid acrylic gases.

Advice for firefighters:

Protective equipment: Wear protective eyewear, gloves, and clothing. Refer to Section 8.

Additional information (precautions): Avoid inhaling gases, fumes, dust, mist, vapor, and aerosols. Avoid contact with skin, eyes, and clothing.

SECTION 6 : Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Ensure adequate ventilation. Ensure that air-handling systems are operational.

Environmental precautions:

Should not be released into environment. Prevent from reaching drains, sewer, or waterway.

Methods and material for containment and cleaning up:

Wear protective eyewear, gloves, and clothing. Refer to Section 8. Always obey local regulations. If necessary use trained response staff or contractor. Evacuate personnel to safe areas. Containerize for disposal. Refer to Section 13. Keep in suitable closed containers for disposal. Use absorbent to collect the material. Wash contaminated surfaces with soap and water.

Reference to other sections:

None

SECTION 7 : Handling and storage

Precautions for safe handling:

Avoid contact with skin, eyes, and clothing. Follow good hygiene procedures when handling chemical materials. Refer to Section 8. Follow proper disposal methods. Refer to Section 13. Do not eat, drink, smoke, or use personal products when handling chemical substances. Contact of resin-based composites with skin should be avoided, especially by anyone having known resin allergies. Avoid eugenol as it will inhibit set. Use only in dry field. Water and oily air will inhibit set and bond. Use a dispensing gun to avoid hand strain.

Conditions for safe storage, including any incompatibilities:

Keep away from food and beverages. Protect from freezing and physical damage. Keep container tightly sealed. Store away from incompatible materials. Do not store composite material in proximity of eugenol-containing products, nor let the composite come into contact with materials containing eugenol. Eugenol can impair the polymerization of the composite and cause discoloration. Refrigerate. Do not freeze. Use at room temperature.

SECTION 8 : Exposure controls/personal protection



Safety Data Sheet

according to 29CFR1910/1200 and GHS Rev. 3

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| | |
|--|---|
| Control Parameters: | 112926-00-8, Silica Amorphous, OSHA PEL 20 mppcf TWA; (80)/(% SiO ₂) mg/m ³ TWA. |
| Appropriate Engineering controls: | Emergency eye wash fountains and safety showers should be available in the immediate vicinity of use or handling. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapor and mists below the applicable workplace exposure limits (Occupational Exposure Limits-OELs) indicated above. |
| Respiratory protection: | Not required under normal conditions of use. Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. When necessary use NIOSH approved breathing equipment. |
| Protection of skin: | Select glove material impermeable and resistant to the substance. Select glove material based on rates of diffusion and degradation. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Use proper glove removal technique without touching outer surface. Avoid skin contact with used gloves. Wear protective clothing. |
| Eye protection: | Wear equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses or goggles are appropriate eye protection. |
| General hygienic measures: | Perform routine housekeeping. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes, and clothing. Before rewearing wash contaminated clothing. |

SECTION 9 : Physical and chemical properties

| | | | |
|---|----------------|---|--|
| Appearance (physical state,color): | Blue Gel | Explosion limit lower: | Not Determined |
| | | Explosion limit upper: | Not Determined |
| Odor: | None | Vapor pressure: | Not Determined |
| Odor threshold: | Not Determined | Vapor density: | Not Determined |
| pH-value: | Not Determined | Relative density: | Not Determined |
| Melting/Freezing point: | Not Determined | Solubilities: | Soluble in water. |
| Boiling point/Boiling range: | Not Determined | Partition coefficient (n-octanol/water): | Not Determined |
| Flash point (closed cup): | > 150°C | Auto/Self-ignition temperature: | Not Determined |
| Evaporation rate: | Not Determined | Decomposition temperature: | Not Determined |
| Flammability (solid,gaseous): | Not Determined | Viscosity: | a. Kinematic: Not Determined b. Dynamic: Not Determined |
| Density: Not Determined | | | |

SECTION 10 : Stability and reactivity

Reactivity: Nonreactive under normal conditions.
Chemical stability: Stable under normal conditions.
Possible hazardous reactions: None under normal processing.

StartFill 2B™

Conditions to avoid: Incompatible materials. Heat, light. Cures on exposure to visible or UV light.

Incompatible materials: Strong acids, alkalies, and oxidizing agents. Free radicals, reducing agents, heavy metal ions.

Hazardous decomposition products: Thermal Decomposition at ~200°C. Combustion creates acrid acrylic fumes.

SECTION 11 : Toxicological information

| | |
|---|--|
| Acute Toxicity: | |
| Oral: | LD50 (Rate)>5000mg/kg |
| Chronic Toxicity: No additional information. | |
| Corrosion Irritation: | |
| Ocular: | Irritation to eyes and skin may be caused by uncured resins. |
| Sensitization: | May cause skin sensitivity in select individuals. |
| Single Target Organ (STOT): | Allergic reactions to methacrylates are possible. |
| Numerical Measures: | No additional information. |
| Carcinogenicity: | No additional information. |
| Mutagenicity: | No additional information. |
| Reproductive Toxicity: | No additional information. |

SECTION 12 : Ecological information

Ecotoxicity None

Persistence and degradability: No information available.

Bioaccumulative potential: No information available.

Mobility in soil: Not determined.

Other adverse effects: None identified.

SECTION 13 : Disposal considerations

Waste disposal recommendations:

Contact a licensed professional waste disposal service to dispose of this material. Dispose of empty containers as unused product. Product or containers must not be disposed together with household garbage. It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities (US 40CFR262.11). Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations. Ensure complete and accurate classification.

SECTION 14 : Transport information

UN-Number

Not regulated

StartFill 2B™

UN proper shipping name

Not regulated

Transport hazard class(es)

Packing group: Not regulated

Environmental hazard: None

Transport in bulk:

Special precautions for user: None

SECTION 15 : Regulatory information

United States (USA)

SARA Section 311/312 (Specific toxic chemical listings):

Acute

SARA Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

RCRA (hazardous waste code): None

of the ingredients are listed.

TSCA (Toxic Substances Control Act):

All ingredients are listed.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

None of the ingredients are listed.

Proposition 65 (California):

Chemicals known to cause cancer:

None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for females:

None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed.

Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

Canada

Canadian Domestic Substances List (DSL):

All ingredients are listed.

Canadian NPRI Ingredient Disclosure list (limit 0.1%):

None of the ingredients are listed.

Canadian NPRI Ingredient Disclosure list (limit 1%):

None of the ingredients are listed.

SECTION 16 : Other information

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations. Note. The responsibility to provide a safe workplace remains with the user. The user should consider the health hazards and safety

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StartFill 2B™

information contained herein as a guide and should take those precautions required in an individual operation to instruct employees and develop work practice procedures for a safe work environment. The information contained herein is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we make no guarantee of results, and assume no liability for damages incurred by the use of this material. It is the responsibility of the user to comply with all applicable laws and regulations applicable to this material.

GHS Full Text Phrases:

None

Abbreviations and acronyms:

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