SAFETY DATA SHEET
CompCore™ AF Twist; Base

1. Chemical Product and Company Identification
   Product Name: CompCore™ AF Twist Nanofill Composite Auto-Cured Core Build-up Material; Base

Premier® Dental Products Company
1710 Romano Drive
Plymouth Meeting, PA  19462
Phone:  610-239-6000     Fax:  610-239-6171

Emergency Phone: 610-239-6000

Indications:
CompCore™ AF is a fluoride releasing, resin composite material designed for the direct fabrication of core build-ups.

Contraindications:
Do not use on patients with known sensitivity or allergy to resins. Wash exposed area completely to remove material. If an allergic reaction is observed, consult a physician immediately and discontinue use with this patient.

2. Hazards Identification
   Acute Health Hazards: May cause eye, respiratory and skin irritation in high concentration.
   Chronic Health Hazards: Material is not known to cause significant health problems
   Signs and Symptoms of Exposure: High concentrations can cause eye and respiratory irritation. Prolonged skin exposure can cause dryness
   Primary routes of exposure: Inhalation, skin contact, eye contact.
   Carcinogenicity: NTP - no, OSHA - no, IARC – no.
   Hazard symbol: ☠

3. Composition / Information on Hazardous Ingredients

<table>
<thead>
<tr>
<th>Hazardous Ingredients</th>
<th>CAS #</th>
<th>Hazard Identification &amp; Risk Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethylenglycoldimethacrylate</td>
<td>109-16-0</td>
<td>Irritant, R36/37/38, R43</td>
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<tr>
<td>Co-initiator</td>
<td>10287-53-3</td>
<td>Irritant, R36/37/38</td>
</tr>
<tr>
<td>Fumed Silica</td>
<td>112945-52-5</td>
<td>R36/37/38</td>
</tr>
</tbody>
</table>

✔ Additional information: For the wording of the listed risk phrases refer to section 16.

4. First Aid Measures
   In case of inhalation: If irritation occurs, take victim to open air. If breathing difficulty persists, consult a physician.
   In case of skin contact: Wash with soap and water.
   In case of eye contact: Flush with large quantities of water for 15 minutes. Consult a physician.
   In case of ingestion: Consult a physician.
5. Fire-Fighting Measures
   Flash point: N/A
   Extinguishing Media: Carbon dioxide, water spray, dry chemical
   Special Fire Fighting Procedures: Avoid a direct jet of water.
   Unusual Fire and Explosion Hazards: None.

6. Accidental Release Measures
   Environmental Precautions: Avoid seepage into sewers and water supplies.
   Clean-Up Procedure: Contain spill and pick up material with a suitable absorbent material. Place absorbent into a container for later disposal.

7. Handling and Storage
   Handling: No special measures necessary if handled according to instruction
   Storage: Keep container tightly closed when not in use. Store in a cool, dry location. Keep material in original packaging.
   Storage away from light, open flames, contamination and prolonged storage above 24°C (75°F).

8. Exposure Controls / Personal Protection
   Exposure Controls: Use only in well-ventilated areas
   Respiratory Protection: Avoid inhalation of vapors. No special protection under normal use.
   Hand and Skin Protection: Avoid unnecessary skin contact. Wear latex gloves when handling
   Eye Protection: Wear safety goggles or safety glasses with side shields when handling,
   Hygiene Measures: Remove spilled material from skin and clothing. Do not eat or drink when handling this material

9. Physical and Chemical Properties
   Appearance: White paste / Light-Yellow paste/ Blue paste.
   Odor: Specific odor
   Boiling Point: N/A
   Evaporation Rate (Water = 1): N/A
   Vapor Density (Air = 1): N/A
   Solubility in Water: Insoluble

10. Stability and Reactivity
    Stability: This material is stable.
    Hazardous Reactions: None if handled according to directions
    Hazardous Polymerization: May occur.
    Conditions to Avoid: Heat, UV light
    Incompatibility: Free radicals, reducing agents, heavy metal ions
    Hazardous Decomposition Products: Carbon dioxide, water, carbon monoxide, acrylic decomposition products, depending on conditions of heating and burning.
11. Toxicological Information
Acute oral toxicity: LD50 (rat) > 5000mg/KG
Irritation of Skin: Dryness and irritation possible upon prolonged exposure
Allergic Effects: Methacrylate sensitive individuals may exhibit an allergic reaction.

12. Ecological Information
Do not discharge into sewers or water supplies
Environmental persistence and degradability: no data available
Ecotoxicity: no data available

13. Disposal Considerations
May be disposed of in landfill or Incinerator In accordance with local, state and federal regulations

14. Transport Information
14.1 Transport at land
ADR
RID
UN Number
Packing Group
Proper shipping name
Kemler Number
14.2 Transport at sea
ADR
RID
UN Number
Packing Group
Proper shipping name
ADNR
IMDG
EMS
MFAG
14.3 Air transport
ADR
RID
UN Number
Proper shipping name
ICAO / IATA-DGR
Subsidiary Risk
Labels
Packing Group

U.S. DOT Shipping Name: Not Regulated
U.S. DOT Hazard Class: None
U.N./N.A. Number: None
U.S. DOT Packing Group: None
Other: Not considered hazardous cargo

15. Regulatory Information
This product requires classification according to the criteria of EC.
The product is a medical device according to the EC-directive 93/42.
15.1 UN Number
15.2 National regulations
15.3 EU number
15.4 Hazard symbols
15.5 Hazard designation
Irritant
15.6 Risk phrases
36/37/38 Irritating to eyes, respiratory system and skin
43 May cause sensitization by skin contact
15.7 Safety phrases
S: 2, 9, 16, 23, 26, 28, 24/25, 37/39
2 Keep out of the reach of children.
9 Keep container in a well-ventilated place.
16 Keep away from sources of ignition - No smoking.
23 Do not breathe vapour.
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.
28 After contact with skin, wash immediately with plenty of water and soap.
24/25 Avoid contact with skin and eyes.
37/39 Wear suitable gloves and eye/face protection.

U.S.-O.S.H.A. Status: This material is not hazardous under the criteria of the U.S Federal Hazard Communication Standard.

16. Other Information

Premier’s revision date: 11/05/2015
Revision number: 8

Relevant R-phrases
36/37/38/43: Irritating to eyes, respiratory system and skin
Irritant

Material should be maintained in original containers. Empty containers should not be re-used.

ANSI/NFPA 704 Data
Fire = 1
Health = 0
Reactivity = 0
Specific Hazard = None

Supplier number: 073014

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