1. Chemical Product and Company Identification

Product Name: CompCore™ AF Stack Cartridge & SyringeMix™ Nanofill Composite Dual-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 an automix, 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 Phases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethylenglycoldimethacrylate</td>
<td>109-16-0</td>
<td>Irritant, R36/37/38/43</td>
</tr>
<tr>
<td>Co-initiator</td>
<td>10287-53-3</td>
<td>Irritant, R36/37/38</td>
</tr>
<tr>
<td>Photoinitiator</td>
<td>10373-78-1</td>
<td>Irritant, R36/37/38</td>
</tr>
<tr>
<td>Fumed Silica</td>
<td>67762-90-7</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
UN Number
Kemler Number
Packing Group
Proper shipping name

14.2 Transport at sea
ADNR
UN Number
IMDG
EMS
Packing Group
Proper shipping name

14.3 Air transport
ICAO / IATA-DGR
UN Number
MFAG
Proper shipping name
Subsidiary Risk
Labels
Packing Group

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: 6

Relevant R-phrases

36/37/38 Irritating to eyes, respiratory system, and skin
43- May cause sensitization by skin contact
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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