SAFETY DATA SHEET

CompCore™ AF Stack Cartridge & SyringeMix™; Base

1. Chemical Product and Company Identification

Product Name: CompCoreTM AF Stack Cartridge & SyringeMixTM 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

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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

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phases
Triethylenglycoldimethacrylate	109-16-0	Irritant, R36/37/38/43
Co-initiator	10287-53-3	Irritant, R36/37/38
Photoinitiator	10373-78-1	Irritant, R36/37/38
Fumed Silica	67762-90-7	R36/37/38

✓ 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** Kemler Number

Packing Group

Proper shipping name

14.2 Transport at sea **ADNR IMDG**

UN Number

EMS MFAG

Packing Group

Proper shipping name

14.3 Air transport ICAO / IATA-DGR

UN Number

Proper shipping name **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

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: 08-14-2014

Revision Number: 4

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

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

 $\begin{aligned} & \text{Fire} = 1 \\ & \text{Health} = 0 \\ & \text{Reactivity} = 0 \\ & \text{Specific Hazard} = \text{None} \end{aligned}$

Supplier's date: 07-15-2014

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