# SAFETY DATA SHEET

CompCore™ AF Stack Cartridge & SyringeMix™; Base

# 1. Chemical Product and Company Identification

Product Name: CompCore<sup>TM</sup> AF Stack Cartridge & SyringeMix<sup>TM</sup> 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<sup>TM</sup> 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 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.

 ${\bf 28} \ {\bf After} \ {\bf contact} \ {\bf with} \ {\bf skin}, \ {\bf wash} \ {\bf immediately} \ {\bf with}$ 

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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