

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

075754270

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

075754106 075754114 075754122 075754155 075754163 075754171 075754254 075754262 075754288 075754304

075754312 075754320 075754361 075754379 075754387 075754403 075754445 075756010

# MATERIAL SAFETY DATA SHEET

CompCore AF Stack Cartridge & SyringeMix; Base

Revision E EU acc. To ISO 11014

Last Revised: 6-19-2011

Approved for Use: 6-20-2011

## 1. Chemical Product and Company Identification

Product Name: **CompCore AF Stack Cartridge & SyringeMix Nanofill Composite Dual-Cured Core Build-up Material; Base**

**Manufacturer:**

**Premier Dental Products Company**

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6000 Fax: 610-239-6171

## 2. Composition / Information on Hazardous Ingredients

Hazardous Ingredients	CAS#	Hazard Identification & Risk Phases
Triethylenglycoldimethacrylate	109-16-0	Xi
Co-initiator	10287-53-3	Xi, R36/37/38
Photoinitiator	10373-78-1	Xi, 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.**

## 3. 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.

## 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 / Gold-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**

**15.6 Risk phrases**

**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

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**

### Xi 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

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This information is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data, or the results to be obtained from use thereof. In no event will the manufacturer or distributor be responsible for damages of any nature whatsoever resulting from the use of, or reliance upon this information. General properties described herein are to be regarded as guides and are not guaranteed for all samples.

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061168 Rev2

# SAFETY DATA SHEET

## CompCore™ AF Stack Cartridge & SyringeMix™; Base

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### 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

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.

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**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**

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**Packing Group**

**Proper shipping name**

**14.2 Transport at sea**

**ADNR**

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**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.**
- 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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The information contained herein is based on our present knowledge. However, this information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Premier Dental Products Company makes no warranties, express or implied with respect to, and assumes no responsibility or liability for, the accuracy or completeness of the information contained herein. Premier Dental Products Company urges persons receiving this information to make their own determination as to the information suitability for their particular application.

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