# MATERIAL SAFETY DATA SHEET

CompCore AF Stack & Flow Cartridge & SyringeMix; Base Revision D *EU acc. To ISO 11014* Last Revised: 12-March-2007 Approved for Use: 13-March-2007

## 1. Chemical Product and Company Identification

Product Name: CompCore AF Stack & Flow 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

CAS#	Hazard Identification & Risk Phases
1565-94-2	N/E
109-16-0	Xi
10287-53-3	Xi, R36/37/38
10373-78-1	Xi, R36/37/38
362603-93-8	N/E
65997-17-3	N/E
7631-86-9	R36/37/38
	1565-94-2 109-16-0 10287-53-3 10373-78-1 362603-93-8 65997-17-3

## ✓ <u>Additional information:</u> 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 instructionStorage: 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**

22 Harmful if swallowed. 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

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.

030719 Rev2

# MATERIAL SAFETY DATA SHEET

CompCore AF Stack & Flow Cartridge & SyringeMix; Catalyst Revision D *EU acc. To ISO 11014* Last Revised: 12-March-2007 Approved for Use: 13-March-2007

## 1. Chemical Product and Company Identification

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

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
Bis-GMA	1565-94-2	N/E
Triethylenglycoldimethacrylate	109-16-0	Xi
Benzoyl Peroxide	94-36-0	Explosive, Xi
Dendritic Polymer	362603-93-8	N/E
Barium aluminoborosilicate glass	65997-17-3	N/E
Fumed Silica	7631-86-9	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 instructionStorage: 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: Light grey 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

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

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	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**

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#### **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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