

## **Safety Data Sheet**

Safety Data Sheet (in compliance with 29 CFR Part 1200 and 29 CFR Part 1020)

Document Number: SDS 007.003 Date Revised: 03/01/24

# 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Alpha II® AP Micro Hybrid Composite

Product Form: Mixture

Part/Item Number: 102-xx01-002 to 102-xx02-002 (xx denotes shade

variances)

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Restorative Composite

Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: Dental Technologies, Inc.

Manufacturer/Supplier Address: 6901 N. Hamlin Avenue

Lincolnwood, IL 60712

Manufacturer/Supplier Telephone Number: 800-835-0885 or 847-677-5500 (Product

Information)

Email address: info@dentaltech.com

1.4 Emergency Telephone Number:

**Emergency Contact Telephone Number:** Chemtrec

800-424-9300 (USA)

001-703-527-3887 (Outside USA)

#### 2. HAZARDS IDENTIFICATION

## 2.1 Classification of the Substance or Mixture:

The product as manufactured is a solid composed of encapsulated chemical ingredients. No hazardous exposures are anticipated during normal product handling and use conditions.

GHS Classification:					
Health Environmental Physical					
Skin Irritant 2 Eye Irritant 2A Skin Sensitizer 1	(H315) (H319) (H317)	Not Hazardous	No Physical Hazards		

EU Classification: Irritant (Xi), R22, R36/37/38, R43

#### 2.2 Label Elements:

SDS-007.003 Page 1 of 8

## Hazard pictograms (GHS-US)



## Signal Word: Danger

Hazard Phrases	Precautionary Phrases	
H315 - Causes skin irritation	P201 - Obtain special instructions before use	
H317 - May cause an allergic skin reaction	P202 - Do not handle until all safety precautions have	
H319 - Causes serious eye irritation	been read and understood	
	P261 - Avoid breathing dust/fume/gas/mist/vapors/spray	
	P264 - Wash thoroughly after handling	
	P272 - Contaminated work clothing should not be	
	allowed out of the workplace	
	P280 - Wear protective gloves/protective clothing/eye	
	protection/face protection	
	P302+P352 - IF ON SKIN: Wash with plenty of soap and	
	water	
	P305+P351+P338 - If in eyes: Rinse cautiously with	
	water for several minutes. Remove contact lenses, if	
	present and easy to do. Continue rinsing	
	P308+P313 - IF exposed or concerned: Get medical	
	advice/attention	
	P321 - Specific treatment (see on this label)	
	P332+P313 - If skin irritation occurs: Get medical	
	advice/attention	
	P333+P313 - If skin irritation or rash occurs: Get medical	
	advice/attention	
	P337+P313 - If eye irritation persists: Get medical	
	advice/attention	
	P362 - Take off contaminated clothing	
	P362+P364 - Take off contaminated clothing and wash it	
	before reuse	
	P405 - Store locked up	
	P501 - Dispose of contents and container in accordance	
	with local and national regulations.	

2.3 Other Hazards: None known.

2.4 Unknown acute toxicity (GHS-US): No data available.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances: Not Applicable

## 3.2 Mixture:

Hazardous Components	C.A.S. #	Classification	WT %
Chemical Frits	7782-41-4	H335	50-75%
Triethylene glycol dimethacrylate	109-16-0	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317	10-30
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1- methylethylidene)di-4,1- phenylene]bis[.omega[(2-methyl- 1-oxo-2-propenyl)oxy]-	41637-38-1	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 STOT SE 3, H335	5-10

SDS-007.003 Page 2 of 8

2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester	1565-94-2	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317	5-10
Diurethane Dimethacrylate	72869-86-4	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317	5-10
2-Hydroxyethyl Methacrylate	868-77-9	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317	1-5

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

## 4. FIRST AID MEASURES

4.1 Description of First Aid Measures:			
Eye	Immediately flush victim's eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.		
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.		
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration and get immediate medical attention.		
Ingestion	Rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.		

## 4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Not expected to present a significant hazard under anticipated conditions of normal use. May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed.

### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required except in cases of high quantities of ingestion or inhalation.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

	Use Chemical Foam, CO2, Dry Chemical Powder, Water Spray. NOTE: Water may be ineffective in extinguishing the fire.
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## **5.2 Special Hazards Arising from the Substance or Mixture:**

Material may burn if exposed to flame.

5.3 Advice for Fire-Fighters:		
Fire Fighting Procedures: Cool fire exposed containers with water spray.		
Precautions for Fire	Firefighters should wear full emergency equipment and approved positive pressure self-	
Fighters:	containing breathing apparatus.	

SDS-007.003 Page 3 of 8

Recommended Protective Equipment for Fire Fighters:				
EYES/FACE HANDS RESPIRATORY THERMAL				
<b>Ey</b>				

### 6. ACCIDENTAL RELEASE MEASURES

## 6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:				
EYES/FACE	HANDS	RESPIRATORY	SKIN	

#### **6.2 Environmental Precautions:**

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities. Avoid contact with skin, eyes or clothing. Avoid breathing vapors. Wear appropriate protective clothing as described in Section 8.

#### 6.3 Methods and Material for Containment and Cleaning up:

Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use non-sparking tools and equipment.

#### 6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

## 7. HANDLING AND STORAGE

## 7.1 Precautions for Safe Handing:

Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly after handling. Keep away from heat, sparks, flames, and other sources of ignition.

## 7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from incompatible materials. Keep container closed to prevent contamination.

**7.3 Specific End Use (s):** No specific end use.

SDS-007.003 Page 4 of 8

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters: No additional information available.

### 8.2 Exposure Controls:

Appropriate Engineering Controls: None required under normal product handling conditions.

#### **Individual Protection Measures (PPE)**

Specific Eye/face Protection: Chemical safety goggles should be worn if needed to avoid eye contact.

**Specific Skin Protection:** Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

**Specific Respiratory Protection:** None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment				
EYES/FACE	HANDS	RESPIRATORY	SKIN	

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on Basic Physical and Chemical Properties:

Physical state:	Solid	Relative density:	1.6g/cc @25°C/77°F
Appearance:	Filled resin	Explosive limits:	Not determined
Odor:	Characteristic	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not determined
рН:	Not determined	Solubility(ies):	Insoluble in water
Melting/freezing point:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Initial boiling point and boiling range:	Not determined	Auto-ignition temperature:	Not determined
Flash point:	Not determined	Decomposition temperature:	Not determined
Evaporation rate:	Not determined	Viscosity:	Not determined

SDS-007.003 Page 5 of 8

Flammability (solid, gas):	Not determined	Oxidizing Properties:	Not determined
<b>Explosive Properties:</b>	Not determined		

9.2 Other Information: None available.

## 10. STABILITY AND REACTIVITY

- 10.1 Reactivity: Stable at ambient temperature and under normal conditions of use.
- 10.2 Chemical Stability: Stable at standard temperature and pressure.
- 10.3 Possibility of Hazardous Reactions: May occur in large quantities.
- 10.4 Conditions to Avoid: Keep away from heat, sparks, flames and other sources of ignition.
- **10.5 Incompatible materials:** High temperatures, visible light sources, strong oxidizing agents. Keep away from sunlight and open flames.
- 10.6 Hazardous Decomposition Products: Oxides of carbon when burned.

#### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on Toxicological Effects:

Triethylene glycol dimethacrylate (109-16-0)		
LD50 oral rat	10837 mg/kg	
ATE (oral)	10837 mg/kg	

Silica, amorphous, fumed, crystalline-free (112945-52-5)		
LD50 oral rat	5000 mg/kg	
ATE (oral)	5000 mg/kg	

Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/irritation	Causes serious eye irritation.
Respiratory or skin sensitization	May cause an allergic skin reaction.
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified

## 12. ECOLOGICAL INFORMATION

- **12.1 Toxicity:** No data available
- 12.2 Persistence and Degradability: No data available
- 12.3 Bio-accumulative Potential: No data available
- 12.4 Mobility in Soil: No data available
- 12.5 Results of PBT and vPvB Assessment: No data available
- 12.6 Other Adverse Effects: No data available

SDS-007.003 Page 6 of 8

## 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: None currently known.

**Waste Treatment Recommendations:** Dispose in accordance with national and local regulations.

#### 14. TRANSPORT INFORMATION

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

#### 15. REGULATORY INFORMATION

## 15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

#### **U.S. Federal Regulations**

Triethylene glycol dimethacrylate (109-16-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester (1565-94-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]- (41637-38-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

## **International Regulations**

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

**European Inventory of Existing Chemicals (EINECS):** This product is a medical device and not subject to chemical notification requirements.

**EU REACH:** All components requiring registration have been pre-registered.

SDS-007.003 Page 7 of 8

**Australian Inventory of Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

**Japanese Existing and New Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**Korean Existing Chemicals List:** This product is a medical device and not subject to chemical notification requirements.

**Philippine Inventory of Chemicals and Chemical Substances:** This product is a medical device and not subject to chemical notification requirements.

**15.2 Chemical Safety Assessment:** None required.

## 16. OTHER INFORMATION

#### HMIS Hazard Rating:

Health: 1	Flammability: 0	Reactivity: 0
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Full text of Classification abbreviations used in Section 2 and 3:

Eye Irrit. 2A	Serious eye damage/ eye irritation Category 2A	
Skin Irrit. 2	Skin corrosion irritant Category 2	
Skin Sens. 1	Skin sensitization Category 1	
STOT SE 3	Specific target organ toxicity (single exposure) Category 3	
H315	Causes skin irritation.	
H317	May cause an allergic skin reaction.	
H319	Causes serious eye irritation.	
H335	May cause respiratory irritation.	

Supersedes: June 1, 2015 Date updated: March 1, 2024

Change Control Document #: DCN 4677, 9306

Revision Summary: June 1, 2015: Converted MSDS to Reach SDS. Updated all sections. March 1, 2024: Updated

to revised GF-404 Rev001 Template. Revised Section 3 to remove non-hazardous components.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical

Bureau, ESIS, Country websites for occupational exposure limits.

## Manufacturer disclaimer:

FOR DENTAL USE ONLY. The information and recommendations are taken from sources (raw material MSDS(s), SDS(s) and manufacturers knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.

SDS-007.003 Page 8 of 8