



# Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Document Number: SDS 013.003  
Date Revised: 06/01/2015

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

**1.1 Product Identifier:**

<b>Trade Name (as labeled):</b>	<b>Alpha-Dent® Hybrid Composite</b>
<b>Product Form:</b>	<b>Mixture</b>
<b>Part/Item Number:</b>	<b>101-xxxx-001 (xx denotes shade and package size variances)</b>

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

<b>Recommended Use:</b>	<b>Restorative Composite</b>
<b>Restrictions on Use:</b>	<b>For Professional Use Only</b>

**1.3 Details of the Supplier of the Safety Data Sheet:**

<b>Manufacturer/Supplier Name:</b>	<b>Dental Technologies, Inc.</b>
<b>Manufacturer/Supplier Address:</b>	<b>6901 N. Hamlin Avenue Lincolnwood, IL 60712</b>
<b>Manufacturer/Supplier Telephone Number: Information)</b>	<b>800-835-0885 or 847-677-5500 (Product</b>
<b>Email address:</b>	<a href="mailto:info@dentaltech.com"><b>info@dentaltech.com</b></a>

**1.4 Emergency Telephone Number:**

<b>Emergency Contact Telephone Number:</b>	<b>Chemtrec</b>
	<b>800-424-9300 (USA)</b>
	<b>001-703-527-3887 (Outside USA)</b>

**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.

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

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

## 2.2 Label Elements:

Hazard pictograms (GHS-US)



**Signal Word:** Danger

Hazard Phrases	Precautionary Phrases
H315 - Causes skin irritation H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have 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-	41637-38-1	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317	5-10

phenylene]bis[.omega.-(2-methyl-1-oxo-2-propenyl)oxy]-		STOT SE 3, H335	
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
Silica, amorphous, fumed, crystalline-free	112945-52-5	Not classified	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:

<b>Eye</b>	Immediately flush victim's eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
<b>Skin</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.
<b>Inhalation</b>	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.
<b>Ingestion</b>	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

### 5.1 Extinguishing Media:





Use Chemical Foam, CO<sub>2</sub>, Dry Chemical Powder, Water Spray. NOTE: Water may be ineffective in extinguishing the fire.

### 5.2 Special Hazards Arising from the Substance or Mixture:



Material may burn if exposed to flame.

### 5.3 Advice for Fire-Fighters:

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

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

## 6. ACCIDENTAL RELEASE MEASURES

<b>6.1 Personal Precautions, Protective Equipment and Emergency Procedures:</b>			
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.			
<b>Recommended Personal Protective Equipment for Containment and Clean-up:</b>			
<b>EYES/FACE</b>	<b>HANDS</b>	<b>RESPIRATORY</b>	<b>SKIN</b>
			

<b>6.2 Environmental Precautions:</b>
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.

<b>6.3 Methods and Material for Containment and Cleaning up:</b>
Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use non-sparking tools and equipment.

<b>6.4 Reference to Other Sections:</b>
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

## 7. HANDLING AND STORAGE

<b>7.1 Precautions for Safe Handling:</b>
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.

<b>7.2 Conditions for Safe Storage, Including Any Incompatibilities:</b>
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.

## 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:

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

<b>Evaporation rate:</b>	Not determined	<b>Viscosity:</b>	Not determined
<b>Flammability (solid, gas):</b>	Not determined	<b>Oxidizing Properties:</b>	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:

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

<b>Silica, amorphous, fumed, crystalline-free (112945-52-5)</b>	
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

### 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.

**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 12, 2006

Date updated: June 1, 2015

Change Control Document #: DCN4677

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

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.