



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 036.002
Date Revised: 12/05/2017

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

1.1 Product Identifier:

Trade Name (as labeled): Alpha-Dent® One-Step Orthodontic Adhesive, Primer & Paste System

Product Form: Mixture

Part/Item Number: 301-0000-001, 301-0001-001, 301- 0003-001, 301-0008-001

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

Recommended Use: Orthodontic Adhesive

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@dentaltch.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 (H315)	Not Hazardous	No Physical Hazards
Eye Irritant 2A (H319)		
Skin Sensitizer 1 (H317)		

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

2.2 Label Elements:

Hazard pictograms (GHS-US)



GHS07

Signal Word: Danger

Hazard Phrases	Precautionary Phrases
H241 - Heating may cause a fire or explosion H315 - Causes skin irritation H316 - Causes mild skin irritation H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation H335 - May cause respiratory 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 %
Triethylene Glycol Dimethacrylate	109-16-0	Skin Sensitization (Cat 1), H317	5-10
2-Propenoic acid, 2-methyl-,(1-methylethylidene)bis{4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester	1565-94-2	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319	30-65
<i>iso</i> -Butyl Methacrylate	97-86-9	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319	10-30
Benzoyl Peroxide	94-36-0	Organic Peroxides (Type B), H241 Eye Irritation (Cat. 2A), H319 Skin Sensitization (Cat 1), H317	1-5
N,N-Bis(2-Hydroxyethyl)-p-Toluidine	3077-12-1	Skin Irritation (Cat. 3), H316 Eye Irritation (Cat. 2A), H319	1-5

Silica	7631-86-9	H335	60-90
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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

5.1 Extinguishing Media:	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 Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.



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

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 Handling:

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.

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 (Paste) / Liquid (Primer)	Relative density:	1.93g/cc;1.03/cc @25°C/77°F
Appearance:	Solid (Paste) / Clear Liquid (Primer)	Explosive limits:	Not determined
Odor:	Characteristic	Vapor pressure (mmHg):	Not determined
Odor threshold:	Not determined	Vapor density:	Not determined
pH:	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
Flammability (solid, gas):	Not determined	Oxidizing Properties:	Not determined
Explosive Properties:	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:

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

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

UN number: N/A

14.2. UN proper shipping name

UN proper shipping name: Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification: N/A

14.4. Packing group

Packing group: N/A

14.5. Environmental hazards

Marine Pollutant #1: N/A

14.6. Special precautions for user

ADR – road: Not Dangerous Goods

RID- rail: Not Dangerous Goods

IMDG – sea: Not Dangerous Goods

IATA – air: Not Dangerous Goods

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

Transport in bulk: Not Dangerous Goods

15. REGULATORY INFORMATION

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

U.S. Federal Regulations

This product is not 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
H315	Causes skin irritation.

H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Supersedes: February 1, 2005

Date updated: December 5, 2017

Change Control Document #: DCN5698

Revision Summary: December 5, 2017: 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.