DENTAL TECHNOLOGIES

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 074.003
Date Revised: 03/15/2018

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

1.1 Product Identifier:

Trade Name (as labeled):	**Alpha-Pro® White Varnish**
Part/Item Number:	**407-0401-002; 407-0501-002; 407-0601-002; 407-0701-002**

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

Recommended Use:	**One step application that reduces dentinal hypersensitivity**
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:	**800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Acute Toxicity Category 2 (H02) Eye Irritant Category 2 (H319) Skin Sensitizer Category 1 (H317) Specific Target Organ Toxicity – Single Exposure Category 3 (H336)	Not Hazardous	Flammable Liquid Category 2 (H225)

EU Classification: Highly Flammable (F), Irritant (Xi), R11, R22, R36, R43, R67

2.2 Label Elements:

Signal Word: Danger

Hazard Phrases	Precautionary Phrases
H225 Highly flammable liquid and vapor H302 Harmful if swallowed H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.	P210 Keep away from heat, sparks, open flames, and hot surfaces. - No smoking. P233 Keep container tightly closed. P261 Avoid breathing vapors. P264 Wash exposed skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection, and face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical attention P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P333+P313 If skin irritation or rash occurs: Get medical attention. P363 Wash contaminated clothing before reuse. P304+P340 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell P330 Rinse mouth. P370+P378 In case of fire: Use carbon dioxide, alcohol resistant foam, dry chemical and water spray to extinguish. P403+P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Rosin	65997-06-0	Not Available	Not Available	60.0 – 80.0%
Ethyl Alcohol	64-17-5	200-578-6	F, Xi R11, R36, R67 Flam. Liq. 2 (H225), Eye Irrit. 2 (H319), STOT SE 3 (H336)	25.0 – 35.0%
Sodium Fluoride	7681-49-4	231-667-8	T, Xi R25, R32, R36/38 Acute Tox. 3 (H301), Eye Irrit. 2 (H319), Skin Irrit. 2 (H315) EUH032	5.0%

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:
May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed. Vapors may cause drowsiness and dizziness.

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 carbon dioxide, alcohol resistant foam, dry chemical and water supply.

5.2 Special Hazards Arising from the Substance or Mixture:
Highly flammable liquid and vapor. Closed containers exposed to heat from fire may build pressure and explode.

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 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): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Hydrogenated Gum Rosin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Ethyl Alcohol	United States	1000 ppm TWA; 1900 mg/m3 TWA
	Germany	200 ppm TWA, 40 ppm STEL DFG MAK
	United Kingdom	400 ppm TWA, 500 ppm STEL UK OEL
	European Union	None Established
Sodium Fluoride (As Fluoride)	United States	2.5 mg/m3 TWA ACGIH TLV 2.5 mg/m3 TWA OSHA PEL
	Germany	1 mg/m3 (Inhalable) TWA, 4 mg/m3 STEL DFG MAK
	United Kingdom	2.5 mg/m3 TWA UK OEL
	European Union	2.5 mg/m3 TWA EU OEL

Biological Exposure Limits: Sodium Fluoride (as fluorides) - Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Use explosion-proof equipment where required.

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:

Appearance:	White opaque viscous liquid	**Explosive limits:**	**LEL:** 2.0 % (2-Propanol) **UEL:** 12.7 % @ 93°C (200°F) (2-Propanol)
Odor:	Characteristic of flavor	**Vapor pressure (mmHg):**	Not Applicable.
Odor threshold:	Not determined	**Vapor density:**	Not Applicable.
pH:	Not determined	**Relative density:**	1.04 g/mL
Melting/freezing point:	Not determined	**Solubility(ies):**	Insoluble in water
Initial boiling point and boiling range:	106°C (228.8°F)	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	16.6°C (61.88°F) Method: Closed Cup	**Auto-ignition temperature:**	Not determined
Evaporation rate:	Not applicable	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Highly flammable under fire conditions	**Viscosity:**	5,000-20,000 cp @ 25°C

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: Contact with acids liberates toxic gas.

10.4 Conditions to Avoid: Keep away from heat, sparks, flames and other sources of ignition.

10.5 Incompatible materials: Avoid acids and oxidizing materials.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, hydrogen chloride and/or hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: May cause moderate irritation with redness, tearing and blurred vision.
Skin: Prolonged or repeated contact may cause mild skin irritation redness, rash and swelling.
Ingestion: Ingestion may cause irritation to the mouth, throat and stomach with abdominal pain and nausea. May cause

gastrointestinal irritation and central nervous system depression with symptoms similar to those described under inhalation.
Inhalation: Inhalation may cause nose and throat irritation with the possibility of central nervous system depression. Symptoms of central nervous system depression include headache, dizziness, drowsiness, nausea and unconsciousness.
Skin: Repeated or prolonged contact may cause irritation, drying, defatting of the skin and dermatitis.
Ingestion: Ingestion of large amounts may cause gastrointestinal upset.
Inhalation: Inhalation of vapors may cause irritation of the mucous membranes and upper respiratory tract.

Chronic Health Effects: Prolonged overexposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Irritation:
Ethanol: Causes serious eye irritation in rabbit eyes. Sodium fluoride: Not irritating to rabbit eyes or skin.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: No data available. This product is not expected to cause sensitization.

Carcinogenicity: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. None of the other components of this product are listed as carcinogens by OSHA, IARC, ACGIH, the EU CLP, or NTP.

Mutagenicity: Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing eye, skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Ethanol: Oral rat LD50- 5045 mg/kg; Inhalation rat LC50 – 16000 ppm /8hr; Skin rabbit LD50- 12800 mg/kg

Sodium Fluoride: Oral Rat LD50-32 mg/kg

Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found.

Specific Target Organ Toxicity (STOT):
Single Exposure: Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salivation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation.
Repeated Exposure: Sodium Fluoride: Brain, liver, kidneys and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:
Ethanol: 96 hr LC50 Fathead minnow – 9640 mg/L; 24 hr EC50 Water flea- 9714 mg/L
Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Water Flea - 98 mg/L

12.2 Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Ethanol: 95% after 21 days- Readily biodegradable.
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	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	UN 1993	Flammable liquids, n.o.s.	3	II	Not applicable
ADR/RID	UN 1993	Flammable liquids, n.o.s.	3	II	Not applicable
IMDG	UN 1993	Flammable liquids, n.o.s.	3	II	Not applicable
IATA/ICAO	UN 1993	Flammable liquids, n.o.s.	3	II	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 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

US OSHA Hazard Classification: Irritant, Sensitizer, Flammable liquid
Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 16,666 lbs (based on the RQ of 1,000 lbs for Sodium Fluoride present at 6%). Report spills required under federal, state and local regulations.
Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification.
Clean Water Act (CWA): This material is not regulated under the Clean Water Act
Clean Air Act (CAA): This material is not regulated under the Clean Air Act
Superfund Amendments and Reauthorization Act (SARA) Title III Information:
SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	**Yes**	**Pressure Hazard:**	**No**

Delayed Hazard:	**No**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

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 –2 Flammability – 3 Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3:
F Highly flammable
T Toxic
Xi Irritant
Xn Harmful
R11 Highly Flammable
R22 Harmful if swallowed
R25 Toxic if swallowed
R32 Contact with acids liberates very toxic gas
R36 Irritating eyes
R43 May cause sensitization by skin contact.
R36/38 Irritating to eyes and skin
R67 Vapors may cause drowsiness and dizziness
Acute Tox. 3 Acute Toxicity Category 3
Acute Tox. 4 Acute Toxicity Category 4
Carc. 2 Carcinogen Category 2
Eye Irrit. 2 Eye Irritant Category 2
Flam. Liq. 2 Flammable Liquid Category 2
Skin Irrit. 2 Skin Irritant Category 2
Skin Sens. 1 Skin Sensitizer Category 1
STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly Flammable Liquid and Vapor
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H351 Suspected of causing cancer.
EUH032 Contact with acids liberates very toxic gas.

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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.