

# TECHNICAL DATA SHEET

<b>Product:</b>	Alpha-Pro® Prophylaxis Paste
<b>Product Description:</b>	A blend of polishing and cleaning agents designed for professional use during standard dental hygiene procedures. It is available in mint and cherry flavors, medium and coarse grit.
<b>Indications for Use:</b>	Fluoride containing prophylaxis paste that gently polishes teeth and removes dental plaque and superficial staining.
<b>Appearance:</b>	Homogeneous thick paste, free from extraneous matter, with flavor and color characteristic of the added flavoring and colorant.
<b>Curing Mechanism:</b>	Not applicable
<b>Shelf-Life:</b>	30 months
<b>Filler Type:</b>	None

<b>Main Composition:</b>	<b>Components</b>	<b>% w/w</b>
	Abrasives	50 – 70
	Humectant	20 – 30
	Water	6 – 12
	Sodium Fluoride	1.30
	Colorant	< 1
	Binder	< 1
	Preservative	< 1
	Sweetener	< 1
	Buffering Agent	< 1
	Flavoring	< 1
	Cleansing Agent	< 1

<b>Physical /Mechanical Properties: (Typical Values)</b>	
Flavor	Match Standard
pH (1:1 aqueous slurry)	8.7
Specific Gravity	1.75
Fluoride Ion, %	0.57
Heavy Metals, ppm	< 20
Relative Enamel Abrasion Grade	8.4 - 12.4
Relative Dentin Abrasion Grade	450 - 640
Ave. Particle Size of Abrasives, $\mu$	
Medium Grit	29
Coarse Grit	34



**Regulatory Classification:**

This product is in conformity with the following standard(s) or other normative documents:

ANSI/ADA Specification No.62: 2005 – Dental Abrasive Paste  
Code of Federal Regulations CFR 21 Part 872 §6030 Oral Cavity Polishing Agent  
Code of Federal Regulations CFR 21 Part 820 – Medical Device Quality System Regulation

**Signature/ Date:**

John Pontikis / 10/24/18

**Name:**

John Pontikis

**Position:**

Management Representative

www.dentaltech.com

ISO 13485

DENTAL TECHNOLOGIES, INC.

6901 N. HAMLIN AVENUE  
LINCOLNWOOD, ILLINOIS 60712 USA

1.800.835.0885 TOLL FREE [US/CANADA]  
1.847.677.5500 PHONE  
1.847.677.5502 FAX

Page 2 of 2  
TDS-049 Rev.004  
Associated Documents: NR 882, DCN 2355, 3673, 5606, 6335