

TECHNICAL DATA SHEET

Product: Alpha II[®] AP Light Cure Micro-Hybrid Composite

Product Description: Alpha II[®] AP is a light cure resin-based micro-hybrid composite with Fluoride.

Alpha II[®] AP is available in 7 Vita[®]* shades plus four opaquers and an incisal shade. The organic matrix oligomer is based on Bis-GMA resin. Alpha II[®] AP is a radio-opaque restorative material that allows for easy identification in radiographs.

Indications for Use: Alpha II[®] AP is recommended for use in Class I and Class II restorations and is

aesthetically accurate for use in Class III, VI, and V restorations.

Appearance: A homogeneous paste available in seven Vita[®] shades plus four opaquers and an

incisal shade.

Curing Mechanism: Light cured by applying an external energy activated Dental Blue Light with

minimum output of 600 mW/cm² and wavelength 400 to 500 nanometers.

Shelf-Life: 30 months

Filler Type: Barium-alumino-boro-fluorosilicate glass and amorphous silica.

Filler % by Volume 53 Filler Particle Range (μ) 0.02 - 2 Average Filler Particle Size (μ) 1

Main Composition (%w/w):

ISO 13485

 $\begin{array}{llll} & & 64-84 \\ Bis-GMA & 6-18 \\ Comonomers & 8-21 \\ Preservative & <1 \\ Colorant & <1 \\ UV \ light \ absorber & <1 \\ Photoinitiator & <1 \\ \end{array}$

Physical /Mechanical Properties:

Water Sorption, $\mu g/mm^3$ 20Water Solubility, $\mu g/mm^3$ 0.60Diametral Tensile Strength, MPa45Compressive Strength, MPa230Flexural Strength, MPa110

Radiopacity, 1 mm disk equivalent to 1 mm aluminum

Depth of cure, mm/2:

Light shades (A1, A2, A3, B1, B2) 2.5 Dark shades (A3.5, Opaquer) 2.3

Regulatory Classification:

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

International Standard ISO 4049: 2019 Dentistry – Polymer-Based Restorative Materials ANSI/ADA Specification No. 27: 2016 Dentistry – Resin-Based Filling Materials

DENTAL TECHNOLOGIES, INC.

6901 N. HAMLIN AVENUE LINCOLNWOOD, ILLINOIS 60712 USA Page 1 of 2 TDS-025 Rev.008 Associated Documents: DCN 1250,1625,3684,5121, 6333, 6384, 6734

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European Standard EN 1641: 2009 Medical Devices for Dentistry – Materials Code of Federal Regulations CFR 21 Part 820 Medical Device Quality System Regulation Code of Federal Regulations CFR 21 Part 872 Dental Devices, Section 3690 Tooth Shade Resin Material

Signature/ Date: _______/ 6/5/19

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Position: Management Representative

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