



TECHNICAL DATA SHEET

Product: Alpha-Dent® Self Cure Composite

Product Description: Alpha-dent® Self Cure Composite Restorative Material contains 57% by volume of a blend of inorganic radio-opaque fillers with particle range from 0.01 to 74 microns. The organic matrix oligomer is based on Bis-GMA resin.

Indications for Use: Alpha-dent® Self Cure Composite Restorative Material is recommended for Class III and Class V restorations and for limited use in Class I restorations in pre-molars and selected Class IV restorations where esthetics is of primary importance.

Appearance: Thick homogeneous paste: White catalyst paste and light brown base paste.

Curing Mechanism: Self cured by mixing base and catalyst together.

Shelf-Life: 36 months

Filler Type: Blend of inorganic fillers

% Filler by volume:	57
Filler particle range, µm	0.01 - 74
Average filler particle size, µm	37

Main Composition (%w/w):

Inorganic Fillers	75 – 85
Bis-GMA	5 – 20
Methacrylate Monomers	3 – 15
Colorant	< 5
Accelerator	< 5
Initiator	< 1
Inhibitor	< 1

Physical /Mechanical Properties: (Typical Values)

Working Time, minutes @ 23 °C	2.3
Setting Time, minutes @ 37 °C	2.5
Compressive Strength, MPa	210
Diametral Tensile Strength, MPa	42
Flexural Strength, MPa	100
Water Sorption, µg/mm ³	20
Water Solubility, µg/mm ³	1

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- Resin Based Filling Material
 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

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