



TECHNICAL DATA SHEET

Product: Alpha-Dent® Self Cure Bonding Adhesive

Product Description: Alpha-Dent® Self Cure Bonding Adhesive is a versatile adhesive that is fast and easy to apply, and offers excellent bond strengths to dentin and enamel.

Indications for Use: Alpha-Dent® Self Cure Bonding Adhesive is designed for bonding composite restorative materials to enamel and dentin.

Appearance: Clear colorless to pale-orange viscous liquid.

Curing Mechanism: Self cured by mixing base and catalyst together in a 1:1 ratio.

Shelf-Life: 48 months

Filler Type: None

Main Composition (%w/w):

Methacrylate Monomers	60 – 80
Bis-GMA	15 – 35
Adhesive Monomer	< 10
Accelerator	< 5
Initiator	< 5
Stabilizer	< 1

Physical /Mechanical Properties:

Working Time at 23 °C, seconds	35
Setting Time at 37 °C, seconds	60
Bond Strength to Dentin, MPa	15
Bond Strength to Enamel, MPa	25

Regulatory Classification:

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

- ISO/TS 11405:2015 Dental Materials – Testing of Adhesion to Tooth Structure
- European Standard EN 1641:2009 – Medical Devices for Dentistry – Materials
- Code of Federal Regulations CFR 21 Part 820 – Medical Device Quality System Regulation

Signature/ Date:

 / 10/24/18

Name:

John Pontikis

Position:

Management Representative