



# TECHNICAL DATA SHEET

**Product:** Alpha-Seal® Light Cure Pit & Fissure Sealant

**Product Description:** Alpha-Seal® is a light cure, resin-based Pit & Fissure Sealant. This sealant contains 50% radiopaque submicron fillers. The hard setting, wear resistant material has an ideal flowable viscosity for maximum coverage and protection to seal the pits and fissures of teeth susceptible to caries.

**Indications for Use:** For sealing pits and fissures on teeth showing no decayed lesions.

**Appearance:** Opaque-white or clear-colorless low viscosity resin.

**Curing Mechanism:** Light cured by applying an external energy activated Dental Blue Light with minimum output 600 mW /cm<sup>2</sup> and wavelength 400 – 500 nanometers.

**Shelf-Life:** 30 months

**Filler Type:** Barium-alumino-silicate glass containing fluoride.

Filler by Volume: 30.30%  
 Filler Particle Range: 0.30 – 0.75 micron  
 Average Filler Particle Size: 0.7 micron

**Main Composition (%w/w):**

Inorganic filler:	45 - 55
Methacrylate monomers:	45 - 55
Accelerator:	<1
Photoinitiator:	<1
UV Stabilizer:	<1
Colorant:	<1

**Physical /Mechanical Properties:**

Sensitivity to ambient light:	>60 sec.
Depth of cure [actual] (typical value):	4.5/20sec.
Compressive strength (typical value):	265 MPa

**Regulatory Classification:**

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

Code of Federal Regulations CFR 21 Part 872.3765 – Pit and fissure sealant and conditioner;  
Code of Federal Regulations CFR 21 Part 820 – Medical Device Quality System Regulation;  
ISO 6874:2005 Polymer-Based Pit and Fissure Sealants

**Signature/ Date:**

 / 5/14/19

**Name:**

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**Position:**

Management Representative

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