



TECHNICAL DATA SHEET

- Product:** Alpha-Dent® Light Cure Pit & Fissure Sealant
- Product Description:** Alpha-Dent® Light Cure Pit & Fissure Sealant is a hard-setting, wear-resistant material having an ideal flowable viscosity for maximum coverage and protection to seal pits and fissures of teeth susceptible to caries. The unfilled, resin-based material fights against recurring caries.
- Indications for Use:** For sealing pits and fissures on teeth showing no decayed lesions.
- Appearance:** A medium viscosity, white, opaque liquid.
- Curing Mechanism:** Light-cured by applying an external energy activated Dental Blue Light with a minimum output of 600 mW/cm² and wavelength of 400 to 500 nanometers.
- Shelf-Life:** 30 months
- Filler Type:** None

Main Composition (%w/w):

Components:	% w/w
Bis-GMA	13 – 33
Diluent comonomers	62 – 82
Adhesive monomer	< 10
Photoinitiator	< 1
Stabilizer	< 1

Physical /Mechanical Properties: (Typical Values):


Appearance	White opaque liquid
Depth of cure mm/40 sec.	1.6

Regulatory Classification:

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

International Standard ISO-6874:2015, Dentistry – Polymer-based Pit & Fissure Sealant
ANSI/ADA Specification No. 39:2006 Pit and Fissure Sealants
European Standard EN 1641:2009, Dentistry – 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 872.3765 Pit and Fissure Sealant and Conditioner

Signature/ Date:

 / 10/24/18

Name:

John Pontikis

Position:

Management Representative