



TECHNICAL DATA SHEET

Product: Alpha-Dent® Cavity Varnish & Sealant

Product Description: Alpha-Dent® Cavity Varnish & Sealant is formulated without chloroform, unlike other products on the market.

Indications for Use: Alpha-Dent® Cavity Varnish & Sealant is designed to form a barrier to protect exposed dentin and reduce fluid leakage around the tooth restoration interface.

Appearance: Clear yellowish liquid with a very strong characteristic odor.

Curing Mechanism: Not applicable.

Shelf-Life: Varnish: 48 months

Filler Type: None

Main Composition (%w/w):

Copal resin solution concentrate	9 – 13
Solvent	80 – 90

Physical /Mechanical Properties: (Typical Values)

Appearance:	Clear liquid
Color:	Straw to pale yellow
% Solids:	10
% Solvent:	90

Regulatory Classification:

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

European Standard BS 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 872.3260 Cavity Varnish

Signature/ Date:  / 10/23/18

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Position: Management Representative