



TECHNICAL DATA SHEET

Product: Alpha-Dent® Polycarboxylate Cement

Product Description: Alpha-Dent® Polycarboxylate Cement is specially formulated for superior strength, resistance to dissolution, and oral retention. It is impervious to oral fluids, and thus permanent under oral conditions.

Indications for Use: Cementation of inlays, onlays, crowns, bridges, and fixed orthodontic bands. Cavity lining under all restorative materials or following root canal treatment. Temporary fillings in deciduous teeth.

Appearance: Fine grit uniform pale yellow powder. Liquid is a clear colorless to pale yellow solution.

Curing Mechanism: Self cured by mixing powder and liquid together.

Shelf-Life: 36 months

Main Composition (%w/w):

Powder:
Zinc Oxide > 90
Magnesium Oxide < 10

Liquid:
Polyacrylic Acid Solution 100

Physical /Mechanical Properties:

Film Thickness, µm < 25
Net Setting Time @ 37 °C, minutes 2.5 – 3.0
Compressive Strength, MPa, minimum 70
Acid-soluble Arsenic, mg/kg < 2
Acid-soluble Lead, mg/kg < 100

Regulatory Classification:

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

- International Standard ISO 9917-1:2007 Dentistry- Water-Based Cements
- 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 Section 3275-Dental Cement

Signature/Date: John Pontikis / 10/18/18

Name: John Pontikis
Position: Management Representative