



TECHNICAL DATA SHEET

Product: Alpha-Dent® Glass Ionomer Cement

Product Description: Alpha-Dent® Glass Ionomer 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. It adheres to dentin, enamel, plastic and non-precious metals.

Indications for Use: Permanent cementation of inlays, crowns, bridges, facing, and orthodontic bands or as a base under any filling material.

Appearance: White fine grit uniform powder. Liquid is a clear colorless to pale yellow viscous solution.

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

Shelf-Life: 36 months

Main Composition (%w/w):

Powder:

Aluminum Fluoride	30-40
Silicon Dioxide	25-35
Aluminum Phosphate	8-16
Aluminum Oxide	15-20
Sodium Fluoride	< 5

Liquid:

Deionized water	40 - 50
Polyacrylic Acid	35 - 45
Tartaric Acid	< 10

Physical /Mechanical Properties:

Film Thickness, µm	< 25
Net Setting Time @ 37 °C, minutes	5.0 - 5.5
Compressive Strength, MPa, minimum	56.50
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

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Position: Management Representative