



TECHNICAL DATA SHEET

Product: Alpha-Dent® Zinc Phosphate Cement

Product Description: Alpha-dent® Zinc Phosphate 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 orthodontics. Cavity lining under all restorative materials.

Appearance: Fine grit uniform powder; available in white or light yellow. Liquid is a clear colorless solution.

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

Shelf-Life: 30 months for liquid and 36 months for powder

Main Composition (%w/w):

Powder:	
Zinc Oxide	> 90
Magnesium Oxide	< 10
Liquid:	
Phosphoric Acid	55 – 85
Deionized water	15 - 30
Hydrated alumina	5 - 10
Zinc Oxide	5 - 10

Physical /Mechanical Properties:

Film Thickness, µm	< 25
Net Setting Time @ 37 °C, minutes	5.5 - 6.0
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 872.3275 – Dental Cement

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

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Position: Management Representative