



TECHNICAL DATA SHEET

Product: Alpha-Cal[®] Calcium Hydroxide Paste with Barium Sulfate

Product Description: Alpha-Cal[®] is an aqueous, radiopaque, high-pH (≥ 12.0) paste packaged in a syringe ready to be dispensed through disposable tips into the root canal. It has a strong antimicrobial effect and it stimulates hard tissue formation within the root canal.

Indications for Use: Alpha-Cal[®] is a Calcium Hydroxide paste with Barium Sulfate used as a root canal sealer for the temporary filling of root canals after conventional endodontic treatments.

Appearance: White to off-white homogeneous soft paste.

Curing Mechanism: N/A

Shelf-Life: 24 months

Filler Type: N/A

Main Composition (%w/w):

Calcium Hydroxide	35 – 50
Barium Sulfate	5 – 20
Thickener	<5
Water	35 - 50

Physical /Mechanical Properties: (Typical Values)

pH (10% aqueous dispersion):	12.4
Tensile Strength (thru # 20-gauge needle), inch:	5
Specific Gravity:	1.40

Regulatory Classification:

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

Code of Federal Regulations CFR 21 Part 820 – Medical Device Quality System Regulation

Signature/ Date: John Pontikis / 10/25/18

Name: John Pontikis
Position: Management Representative