

TECHNICAL DATA SHEET

Product: Alpha-TCemTM NE Non-Eugenol Cement

Product Description: Alpha-TCemTM NE is a non-eugenol temporary cement. Alpha-TCemTM NE is

designed for temporary cementation of crowns, bridges, inlays and onlays. It offers strong adhesion to the tooth yet allows easy removal of the temporary restoration.

Indications for Use: Alpha-TCemTM NE is indicated for temporary cementation of provisional crowns,

bridges, inlays, and onlays.

Appearance: 1:1 ratio (by volume), 2-paste system

Accelerator: amber, translucent

Base: white, opaque Shade: off-white

Curing Mechanism: Chemically cured by mixing base and accelerator together.

Shelf-Life: 24 Months

ISO 13485

Filler Type: Starch and silica

Main Composition (%w/w): Base: %

 $\begin{array}{lll} \text{Zinc Oxide} & 50-60 \\ \text{Starch} & 20-30 \\ \text{Natural Oils} & 15-25 \end{array}$

Physical /Mechanical Properties: Working time: ≥2 min. at 23°C

Setting time: ≤5 min. 30 sec. at 37°C

Compressive strength: ≤35 MPa at 24 h

Film thickness: $\leq 25 \mu m$ Acid-soluble arsenic content: $\leq 2 mg/kg$

Regulatory Classification:

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

International Standard ISO 3107:2011 Dentistry – Zinc Oxide/Eugenol and Zinc Oxide/non-Eugenol Cements European Standard EN 1641:2009 – Medical Devices for Dentistry – Materials Code of Federal Regulations 21CFR Part 820 – Medical Device Quality System Regulation

Signature/ Date: ______/ 10/25/18

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Position: Management Representative

DENTAL TECHNOLOGIES, INC.

6901 N. HAMLIN AVENUE LINCOLNWOOD, ILLINOIS 60712 USA Page 1 of 1 TDS-101 Rev.001 Associated Documents: NR 2374, DCN 6341

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