

TECHNICAL DATA SHEET

Product: Alpha-Pro[®] White Varnish

Product Description: Alpha-Pro[®] White Varnish contains 5% sodium fluoride. It is used in the treatment

of dentinal and post operative sensitivity. Alpha-Pro[®] White Varnish, when applied, practically becomes invisible, unlike traditional varnishes that cause unsightly yellow coloring of the teeth. Alpha-Pro[®] White Varnish sets immediately on contact with saliva, leaving a smooth, thin layer. It is available in bubblegum, melon, mint,

and strawberry flavors.

Indications for Use: For treatment of dentinal and post operative sensitivity.

Appearance: White to off-white, medium viscosity liquid.

Curing Mechanism: N/A

Shelf-Life: 30 months

Filler Type: N/A

ISO 13485

Main Composition (%w/w):

Colophony: 45 - 60
Ethyl Alcohol: 20 - 35
Sodium Fluoride: 5
Emulsifier: 2 - 7
Flavor: 2 - 5
Xylitol: <1
Sweetener: <1

Physical /Mechanical Properties:

Appearance: Medium viscosity liquid Color: White to off-white

Odor: Characteristic of ethanol and specific flavor Flavor: Bubblegum, melon, mint or strawberry

% Sodium Fluoride: 5

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; Code of Federal Regulations CFR 21 Part 872.3260 – Cavity varnish.

Signature/ Date: ______/ 10/25/18

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Position: Management Representative

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