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The Potential for Allergic Cross-Reactions to Colophony Contained in Vanish Varnish, in Patients with Allergic Reactions to Pine Nuts.

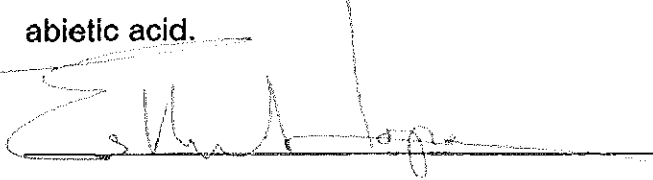
Vanish® 5% NaF White Varnish is an in-office dental varnish. An inactive ingredient of Vanish Varnish is "Pentaerythritol Glycerol Ester of Colophony", which is a modification of the naturally occurring rosin (colophony) derived from pine tree sap.

Unmodified colophony is known to cause allergic dermatitis in some people. Pine nuts are known to cause allergic responses in some people, and recent publications indicate that exposure to pine nuts may elicit a hypersensitivity response in people who are allergic to pine pollen, and vice versa. Because of this potential cross-reactivity, there have been concerns that dental patients who are allergic to pine nuts or pine pollen may react to the modified colophony contained in products such as Vanish Varnish.

The Toxicology Assessment and Compliance Assurance Group within the 3M Medical Department has reviewed the available information on colophony, pine nuts and pine pollen and also reviewed the scientific literature on hypersensitivity responses. 3M's Toxicology Assessment and Compliance Assurance Group believes there is minimal chance that Vanish Varnish will elicit an allergic reaction in patients who are allergic to pine nuts or pine pollen. The allergen(s) of pine nuts/pollen have not been precisely identified, but they are known to be small proteins (peptides). The allergic components of colophony have been identified as abietic acid and related compounds of similar molecular structure.

Polycyclic carboxylic acids such as abietic acid are chemically quite different from the peptides responsible for pine nut hypersensitivity. The allergic cross-reactivity that can occur among the various tree nuts does not occur between such different chemical classes as the abietic acids and the pine nut peptides.

In addition, the allergic potential of Vanish Varnish is minimized by the use of the pentaerythritol glycerol ester of colophony, rather than unmodified colophony. Esterification of colophony is documented to reduce the allergenic potential of abietic acid.

A handwritten signature in black ink, appearing to read "Esther F. Hope", written over a horizontal line.

Esther F. Hope, DVM, Diplomate, American Board of Toxicology
3M Toxicology Assessment and Compliance Assurance