

ALLERGENS FACT SHEET

Applying FluoroDose 5% Sodium Fluoride varnish is an effective step of an overall comprehensive oral care and prevention program. From time to time, questions are asked about the composition of the FluoroDose material and the concern for allergic reactions.

FluoroDose contains processed pine rosin, or colophony, the sticky sap from conifer trees. Rosin or colophony has a wide application in many industries, including pharmaceuticals, because of its properties to stick to other substances. For that reason, colophony is a major ingredient in the FluoroDose formulation, as it can block dentin tubules to treat tooth sensitivity. It helps the varnish remain on the tooth for 4-6 hours, which is the optimal time for the sodium fluoride ingredient to release and be taken up by the enamel.

Allergic reactions to rosin or colophony are known to the medical community, and our instructions specifically advise the health care professional of this risk.

When applying any sodium fluoride varnish, including FluoroDose, clinicians should take a patient's tolerance to this material, as well as their health history, into consideration. The FluoroDose instructions, as previously noted, contra-indicate for patients with known colophony and sodium fluoride allergies. FluoroDose also contains beeswax which may affect the decision to use this product.

Equally important is providing information on common allergens which are not present in the FluoroDose formulation and this information is given in the chart below:

COMMON ALLERGENS	PRESENT IN FLUORODOSE ¹
Dairy Products (including derivatives)	No
Egg Products	No
Gluten (including wheat, barley, millet & rye)	No
Soy Products (including soy lecithin)	No
Peanut Products	No
Tree Nuts & Derivatives (including almond, Brazil nut, cashew, chestnut, hazelnut/filbert, macadamia, pecan, pine nuts, pistachio, walnut)	No
Seed Products (including sesame, sunflower, cottonseed, poppy)	No
Dyes (including FD&C Red Dye 40)	No

It has been brought to our attention that there is some confusion between pine rosin and pine nut allergies. As indicated above, pine rosin (colophony) and pine nuts are known allergens, each with their own presentation of symptoms and treatments. Following a thorough scientific literature review, we do not find any evidence to suggest that having allergies to pine nuts automatically makes the patient allergic to pine rosin. The suspected allergens in pine nuts are different than those in pine rosin because the chemical composition of each is different from the other, and the sources from where each originates is also different.

Our objective at Centrix is to provide as much safety information as possible regarding the use of our products through the use of cautions and contra-indications found in our instructions. In those cases where we are unable to provide specific warnings for specific ingredients, we strongly encourage that an allergen patch screening test be performed using our material to make the best judgement for the patient.



Tim White | Regulatory Affairs Manager

¹Although there are no allergens present in the product itself, the above allergens may be present in the same facility and/or manufacturing equipment used to produce the raw materials and/or finished product. ©2026 Centrix, Inc. | 018191 REV B