February 12, 2020

None of the listed allergens are ingredients in FluoriMax® 2.5% NaF Varnish:

- Milk
- Dyes
- Glutens
- Eggs
- Peanuts
- Tree nuts
- Pine
- Fish
- Shellfish
- Soy
- Wheat
- Sunflower seeds
- Corn
- Sesame seeds

The pharmaceutical facility where FluoriMax Varnish is manufactured does not process any of the potential allergens listed above, therefore there is no risk of cross-contamination. The facility fills products that contain Lactokine™ (a milk protein) and antibiotics, however, the equipment used to process and fill FluoriMax does not fill products with either of these additives.

FluoriMax does not contain tree-based or synthetic rosins which may cause an allergic reaction. FluoriMax is the only U.S.-marketed fluoride varnish that utilizes a shellac resin. Shellac is commonly used in food and cosmetic products and is well-tolerated by the body.

FluoriMax contains one half (2.5%) of the typical amount (5.0%) of sodium fluoride due to research which demonstrates enamel reaches a saturation point with an effective 2.5% NaF varnish\(^1\). In addition, there has been a call for lowering the concentration per application\(^2\), especially when used on pediatric patients.

Sincerely,

Steve Pardue

1. Seppa et. al., Caries Research 1994; 28; 64-67
2. Ahmed, Coleman, Carey, IADR 2013, 3259