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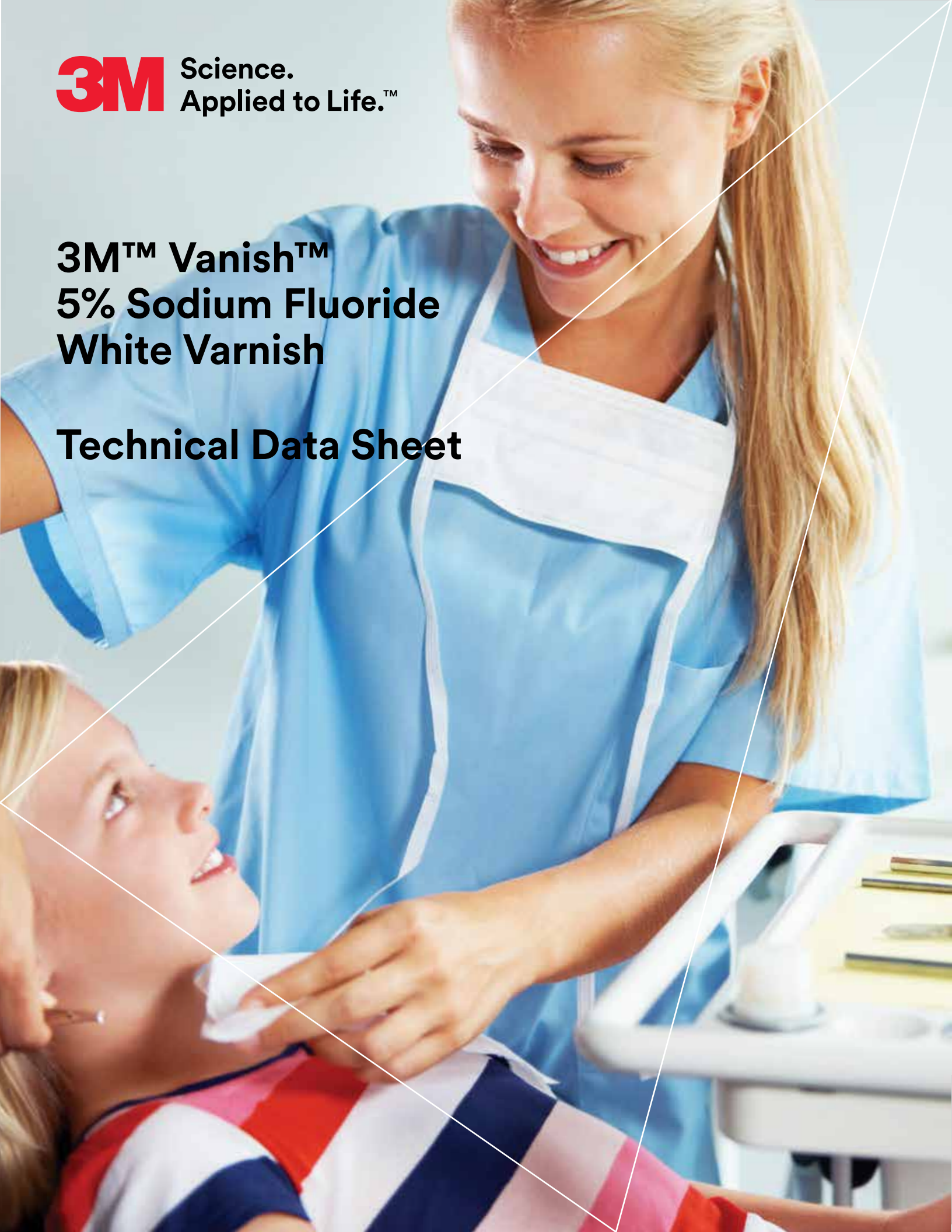
3M™ Vanish™ 5% Sodium Fluoride White Varnish

Technical Data Sheet



Available in Mint, Melon and Cherry flavors. Convenient, single-use packaging.

3M™ Vanish™ 5% Sodium Fluoride White Varnish Extended Release Formula

Vanish White Varnish is a fluoride-containing varnish with added calcium and phosphate that can be applied to enamel and dentin and is virtually invisible when applied to the teeth. The product is saliva-activated; it will adhere to dry or moist teeth and spread after application. The patented formula contains a modified rosin, which migrates across tooth surfaces, including surfaces that are difficult to reach. Vanish White Varnish is an extended release formula that shows continual release of fluoride up to 24 hours after application.

Summary of Advantages:

- The #1-selling fluoride varnish in the U.S.
- Extended fluoride release—22,600 ppm sodium fluoride
- Added calcium and phosphate (TCP)
- Contains xylitol
- No need to dry tooth surface
- Can be applied to tooth surfaces where plaque is present
- Can be applied with a swiping technique—no need to paint individual tooth surfaces
- Unique applicator for back-of-glove dispensing
- Migrates to hard-to-reach areas
- Relieves hypersensitivity
- Does not change appearance of metal or ceramic orthodontic brackets
- Over 10 years of clinical success

Composition

3M™ Vanish™ 5% Sodium Fluoride White Varnish contains 5% sodium fluoride and an innovative tri-calcium phosphate ingredient, which is sold exclusively through 3M. Fluoride, calcium and phosphate are all minerals found in saliva and all are necessary for building strong teeth.[1] The varnish is an alcohol-based suspension of modified rosin. Vanish White Varnish is sweetened with xylitol. The product is supplied in unit-dose packages containing 0.5 ml (0.5 grams) of Vanish White Varnish. Each 0.5ml dose contains 25 mg of sodium fluoride, equivalent to 11.3 mg of fluoride ion.

Patient Instructions

- **For best results, do not brush or floss your teeth for 24 hours.**
- **Eat soft foods during the treatment period.**
- **Do not consume hot drinks or alcohol (including mouth rinses) during the treatment period.**
- **After the treatment period, you can remove the varnish by brushing and flossing.**

Procedure

Vanish White Varnish is unique among conventional fluoride varnishes. It's quick and easy to apply because there's no need to dry tooth surfaces before application, and it can be applied with a sweeping brush stroke—with no need to paint each individual tooth surface. The handling properties of Vanish White Varnish allow it to be dispensed from the back of a gloved hand for added convenience.

1. Vanish White Varnish can be applied to tooth surfaces where plaque is present. A prophylaxis is not required.
2. Open the unit-dose package of Vanish White Varnish and dispense the entire contents. Use the applicator brush to thoroughly mix the varnish, since components of all sodium fluoride varnishes can separate during storage.
3. Apply the product to the teeth in a thin layer with the supplied brush. Apply the varnish with sweeping horizontal brush strokes. Avoid excessive contact with soft tissue. It is not necessary to use all of the varnish provided. Use only enough varnish to form a thin coating on the desired treatment area.
4. After application, instruct the patient to close their mouth to set the varnish. Rinsing or suctioning immediately after application is not recommended. You may see a thin coating on the teeth. The patient may feel the thin coating when rubbing the treated area with their tongue.
5. The treatment period for Vanish White Varnish is a minimum of 4 hours. Left undisturbed, Vanish White Varnish will continue to release fluoride, calcium and phosphate for 24 hours.
6. To achieve the maximum benefit after application, please advise the patient to follow the Patient Instructions above.

Open the unit-dose package and dispense the entire contents onto a mixing surface. For easy application, squeeze onto the gloved hand like a painter's palette, so you can efficiently deliver varnish to the patient.

IMPORTANT: Use the applicator brush to thoroughly mix Vanish White Varnish, since components of all sodium fluoride varnishes can separate during storage. While mixing, keep the material evenly distributed.

Apply Vanish White Varnish evenly in a thin layer over treatment area(s) with sweeping, horizontal brush strokes. No suction required. Refer to Instructions for Use for complete details.

Properties

Relief of Dentinal Hypersensitivity

3M™ Vanish™ 5% Sodium Fluoride White Varnish creates a barrier that provides immediate and sustained occlusion of dentinal tubules as shown by the magnified SEM images below.

Vanish White Varnish covers and occludes open tubules (Figure 1). After the varnish has been removed, Vanish White Varnish can be seen occluding the tubule openings (Figure 2). A cross-sectional image shows that Vanish White Varnish penetrates deep into the dentinal tubules (Figure 3). This penetration prevents the flow of fluid and the transmission of ions in the tubules, which results in a subsequent reduction in pain.

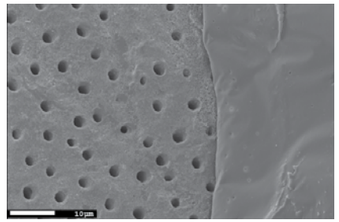


Figure 1: (1500x magnification)

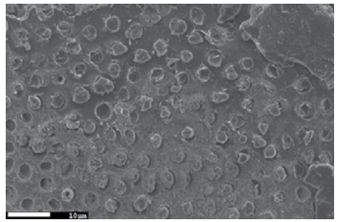


Figure 2: (1500x magnification)

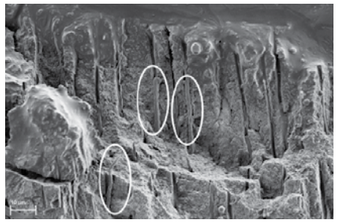


Figure 3: (2000x magnification)

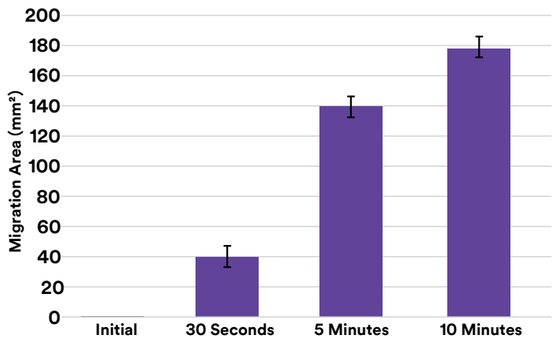
Source: 3M internal data

Adhesion and Migration

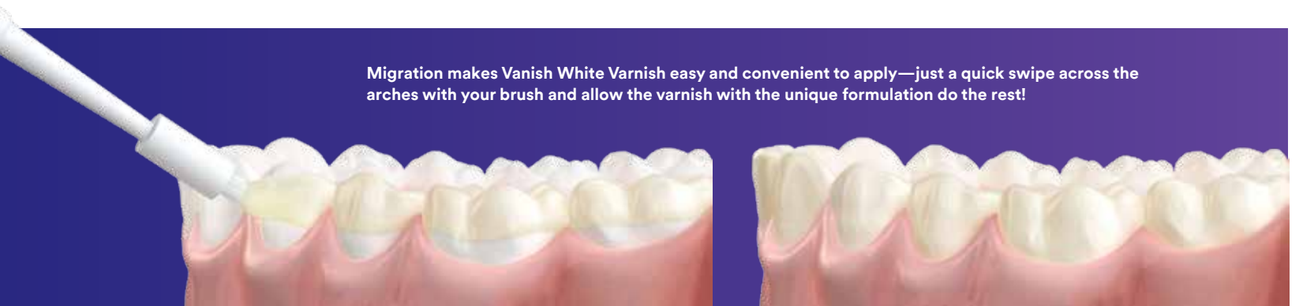
Vanish White Varnish spreads to additional tooth surfaces after application. This is an advantage in the treatment of interproximal and other hard-to-reach treatment areas. In the following clinical study,[2] migration of Vanish White Varnish began almost immediately after application and continued for at least four hours, the duration of the study and the minimum amount of time the product should remain on the teeth. Vanish White Varnish spread to more than double the number of surfaces to which it was initially applied, demonstrating the in vivo migration of the product. Additionally, a laboratory test has been developed to demonstrate the migration of the coating by measuring the distance and area of varnish flow once it comes into contact with water (or saliva) after it is applied.

In Vitro Migration Area of Vanish White Varnish Over 10 Minutes

(n = 3, +/- standard deviation)



Source: 3M internal data



Extended Release

As 3M™ Vanish™ 5% Sodium Fluoride White Varnish slowly wears away, the sodium fluoride, calcium and phosphate in the coating dissolve and are released as ions. Fluoride ions react with the calcium naturally occurring in the saliva[1] or the calcium released from Vanish White Varnish. The fluoride ions and the calcium ions combine to form insoluble globules of calcium fluoride that block exposed dentin tubules for sustained relief of tooth hypersensitivity.[3]

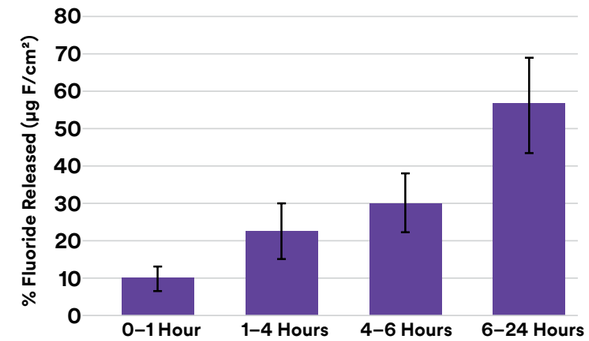
The formation of tooth mineral is enhanced by the slow release of fluoride from varnish.[4] The ongoing presence of varnish on the tooth provides time for calcium fluoride to convert into tooth mineral. Laboratory testing has shown, when fluoride is exposed to enamel for long periods of time, the efficiency of the fluoride is increased and the mineral produced is more acid resistant.[5] Vanish White Varnish continually releases fluoride, calcium and phosphate for 24 hours after application.[6]

A fluoride varnish should have the following properties:[7]

- The ability to maintain a physical barrier for a given period of time
- Provide controlled release of low fluoride levels to the tooth (i.e. steady exposure of low levels of fluoride provide clinical benefits)

Cumulative In Vitro Fluoride Release of Vanish White Varnish Over 24 Hours by Time

(n = 3, +/- standard deviation)



Source: 3M internal data

The Role of Calcium and Phosphate

Calcium and phosphate are naturally occurring components of saliva long associated with maintaining healthy teeth.[1] When calcium and phosphate combine, they create hydroxyapatite. When calcium and phosphate combine with fluoride, they create fluorapatite, a stronger, more acid-resistant mineral.

Calcium and fluoride have a strong natural affinity for one another and combine easily when in close proximity.[8] Some other products that combine calcium and fluoride into one product experience the minerals combining prematurely within the package, meaning the minerals are no longer available to combine on the tooth surface.

Fluoride:
Cementing the building blocks of healthy teeth

Incorporating fluoride into enamel makes it more resistant to acid attack.

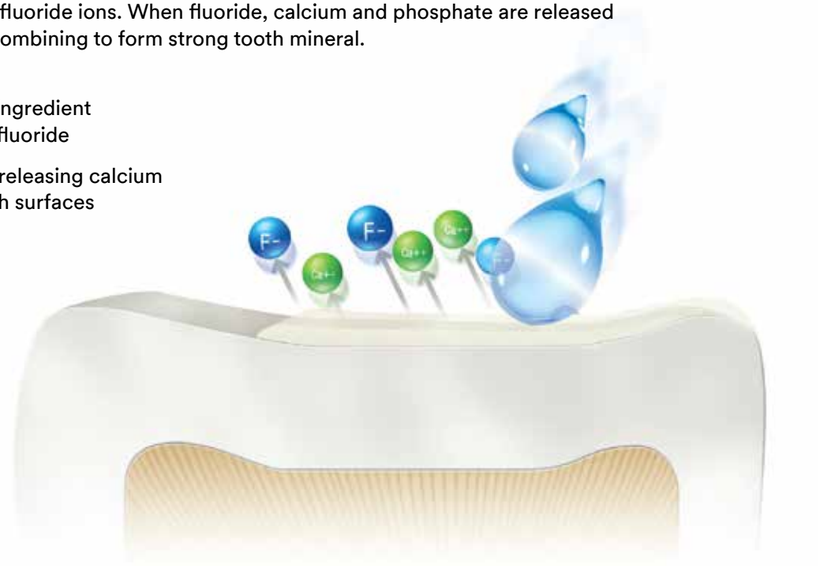
= Calcium + Phosphate Mineral $Ca_{10}(PO_4)_6(OH)_2$ = Hydroxyapatite

= Calcium + Phosphate + Fluoride Mineral $Ca_5(PO_4)_3F$ = Fluorapatite

Why TCP?

3M™ Vanish™ 5% Sodium Fluoride White Varnish contains an innovative tri-calcium phosphate ingredient available exclusively from 3M. When the tri-calcium phosphate ingredient is added to Vanish White Varnish, a protective coating on the minerals ensures the calcium and fluoride do not combine prematurely. This protective coating continues to work throughout the shelf life of the varnish. After Vanish White Varnish is applied to the tooth surface and is exposed to saliva, the protective coating slowly dissolves, allowing the calcium and phosphate to be released together with fluoride ions. When fluoride, calcium and phosphate are released together, they have a better chance of combining to form strong tooth mineral.

- A 3M proprietary calcium phosphate ingredient designed to work in conjunction with fluoride
- Protective coating dissolves in saliva, releasing calcium and phosphate to join fluoride on tooth surfaces



Contains 22,600 ppm fluoride and tri-calcium phosphate to enhance the natural mineral content of saliva needed for building strong teeth.

Performance

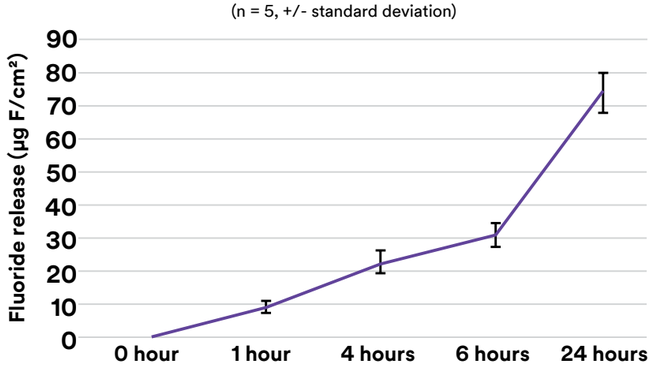
Internal and third-party test data show favorable performance results for Vanish White Varnish.

Fluoride Release

Laboratory testing demonstrates that Vanish White Varnish releases fluoride consistently for 24 hours when the coating is left in place. After 24 hours, Vanish White Varnish still has the ability to release fluoride from the remaining coating. You can be confident your patients are protected long after they leave your dental chair.

Cumulative Fluoride Release of Vanish White Varnish Over 24 Hours

(n = 5, +/- standard deviation)



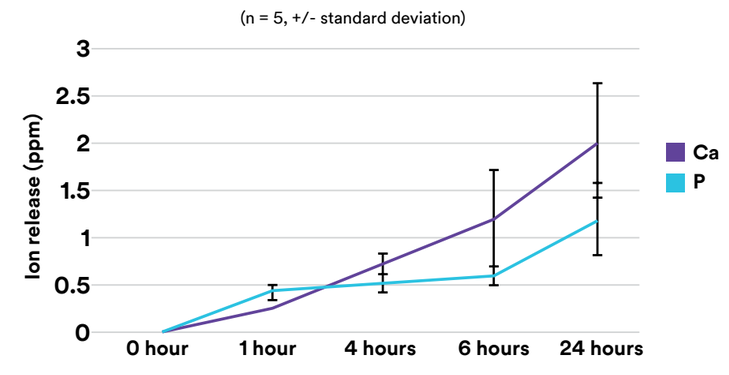
Source: 3M internal data

Calcium and Phosphate Release

Calcium and phosphate are essential for building strong tooth mineral. 3M™ Vanish™ 5% Sodium Fluoride White Varnish contains added calcium and phosphate and releases these minerals from the varnish coating alongside fluoride, so all three minerals are able to interact. Laboratory testing demonstrates Vanish White Varnish releases calcium and phosphate for 24 hours when the coating is left in place.

In Vitro Calcium and Phosphorous Release From Vanish White Varnish Over 24 Hours

(n = 5, +/- standard deviation)



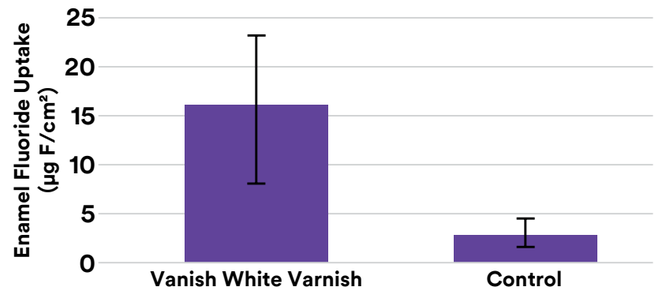
Source: 3M internal data

Fluoride Uptake

Fluoride uptake is the ability of fluoride to be absorbed into the tooth and thus be incorporated into the mineral. Laboratory testing using a model similar to FDA Method 40 for enamel fluoride uptake demonstrates the fluoride in Vanish White Varnish can be absorbed by lesioned enamel.

In Vitro Enamel Fluoride Uptake of Vanish White Varnish After 4-Hour Dynamic Model

(n = 10, +/- standard deviation)



Source: 3M internal data

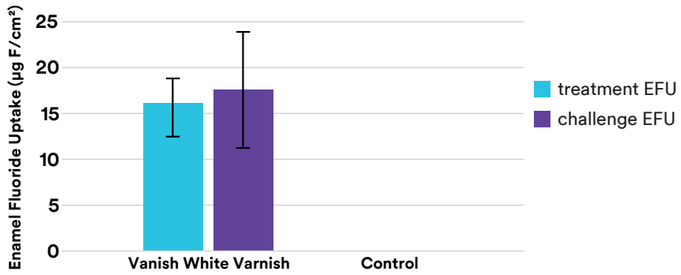
Method used for fluoride uptake: Bovine enamel specimens with artificial lesions were placed into stratified treatment groups (n=10) based on Vickers surface-microhardness (4×200g-load-15sec). Samples were treated with varnish and submerged in artificial saliva. The artificial saliva was removed and replaced with fresh artificial saliva at 0.25, 0.50, 1.0, 2.0 and 4.0 hours to simulate saliva flow during treatment. After 24-hour samples were challenged with lactic acid (pH=5.0) for 24 hours, fluoride uptake (microdrill biopsy 100µm deepx1mm diameter) and Vickers microhardness were measured after treatment and after acid attack.

Fluoride Uptake After Acid Challenge

Laboratory testing confirms that fluoride absorbed into lesioned enamel is still present after a 24-hour acid challenge. Fluoride is found throughout the lesion and not only on the surface of the enamel.

In Vitro Enamel Fluoride Uptake for 3M™ Vanish™ 5% Sodium Fluoride White Varnish After 24-Hour Static Model and Acid Challenge

(n = 10, +/- standard deviation)



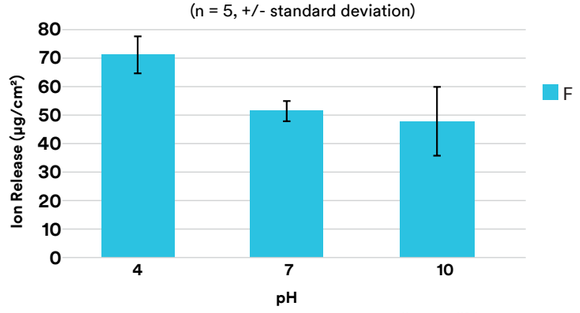
Source: 3M internal data

Release During Acid Challenge

The pH of the mouth changes throughout the day and can vary greatly between patients. The pH in the mouth is important because enamel and dentin can begin to dissolve at a pH of 5.5. Dentin dissolves even faster due to its porous structure.[9] Laboratory testing demonstrates Vanish White Varnish releases even more fluoride, calcium and phosphate in the acidic environment (at a lower pH). This means Vanish White Varnish does its best work when the mouth is most vulnerable.

Vanish White Varnish Releases Even More Fluoride in the Acidic Environment (lower pH)

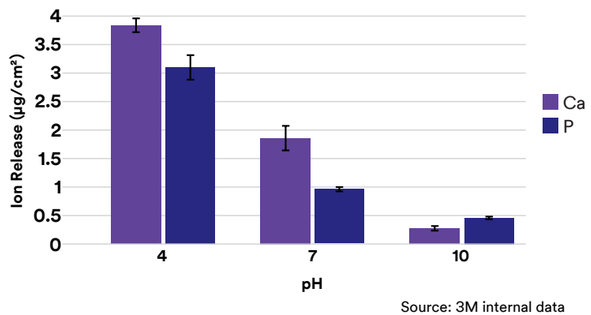
(n = 5, +/- standard deviation)



Source: 3M internal data

Vanish White Varnish Releases Calcium and Phosphate in the Acidic Environment

(n = 5, +/- standard deviation)



Source: 3M internal data

Frequently Asked Questions

What advantages does 3M™ Vanish™ 5% Sodium Fluoride White Varnish offer over other fluoride varnishes?

Vanish White Varnish contains 22,600 ppm fluoride and an innovative tri-calcium phosphate ingredient, available exclusively from 3M. A protective coating is added to the tri-calcium phosphate. This protective layer keeps it separate from the fluoride in the varnish to prevent the minerals from prematurely combining. After Vanish White Varnish is applied to the tooth surface, the protective coating slowly dissolves and releases fluoride, calcium and phosphate ions into the saliva. Fluoride and calcium react to form calcium fluoride.

Vanish White Varnish creates a durable coating that adheres to teeth and also migrates to additional tooth surfaces. The varnish contains a modified rosin in an alcohol-based solution that allows Vanish White Varnish to adhere to the teeth to which it has been applied and yet migrate to additional tooth surfaces, including areas of the mouth that may be difficult to reach.

Vanish White Varnish is virtually invisible on the tooth. The product is white in color when applied to the tooth. Clinical studies show 95% of subjects rated the appearance of Vanish White Varnish to be acceptable after application.

Vanish White Varnish can be applied to moist tooth surfaces and to tooth surfaces where plaque is present. Saliva activates the varnish and forms a coating on the tooth surface.

What is the role of calcium and phosphate in Vanish White Varnish?

The added calcium and phosphate in Vanish White Varnish increases the likelihood of forming calcium fluoride globules on tooth surfaces.

How is Vanish White Varnish packaged?

Vanish White Varnish is supplied in single unit-dose packages to eliminate the problems of product separation that may occur in large, multi-dose containers. Unit-dose packaging also eliminates the chance of cross-contamination. You can be assured each unit-dose contains the correct amount of fluoride. Use the applicator brush to thoroughly mix Vanish White Varnish prior to application, as all sodium fluoride varnishes separate during storage.

How often should I apply Vanish White Varnish?

Many dental professionals apply Vanish White Varnish twice a year, but the product can be applied more frequently if needed. Vanish White Varnish is safe to use four times per year for patients 6 years of age and older.

Will my patients notice Vanish White Varnish on their teeth?

Patients may feel a thin coating of varnish on their teeth when rubbing the treated area with the tongue. Patients may see a thin coating when looking at the teeth, but for most patients, Vanish White Varnish is not noticeable in appearance.

How long should my patients leave Vanish White Varnish on their teeth?

The recommended treatment period for Vanish White Varnish is a minimum of 4 hours, up to 24 hours. The coating will naturally wear away in that time period. In laboratory studies, Vanish White Varnish continues to release fluoride, calcium and phosphate for 24 hours. Patients should refrain from brushing or flossing their teeth for 24 hours to achieve the maximum benefit.

Frequently Asked Questions
(Continued)

Can patients undergoing orthodontic treatment use 3M™ Vanish™ 5% Sodium Fluoride White Varnish?

Patients undergoing orthodontic treatment with traditional metal or ceramic brackets may use Vanish White Varnish. Laboratory testing demonstrates that Vanish White Varnish has the ability to migrate around orthodontic banding. Patients who use removable clear tray aligners should refrain from using rosin-based varnishes, as these products will stick to the aligner.

Can my patients eat after application of Vanish White Varnish?

Patients can eat immediately after application of Vanish White Varnish. They should avoid eating foods that are hard or sticky and drinking beverages that are hot or contain alcohol. This includes the use of mouth rinses containing alcohol.

Should patients stop using fluoride rinses or supplements after application of Vanish White Varnish?

Patients should not use prescriptive fluoride preparations such as gels or rinses for 24 hours after application of Vanish White Varnish. Children who are taking fluoride supplements should discontinue use of these supplements for 2–3 days following treatment with Vanish White Varnish.

Are there any contraindications to the use of Vanish White Varnish?

As with other fluoride varnishes, Vanish White Varnish should not be applied to patients with ulcerative gingivitis (ANUG) or stomatitis. Patients with a known allergy to colophony/rosin should avoid this product.

What is the best way to remove Vanish White Varnish if it accidentally gets on my dental instruments or equipment?

A small amount of rubbing alcohol or alcohol-based hand sanitizer will remove the product from unwanted surfaces.

References

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