

## **SMILE ACTIVE PRO TARTAR CONTROL FLUORIDE- sodium fluoride paste** **Guthy-Renker LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Smile Active Pro Tartar Control Fluoride Toothpaste**

#### **Drug Facts**

##### **Active ingredient**

Sodium Fluoride 0.248% (0.15% w/v fluoride ion)

##### **Purpose**

Anticavity

##### **Use**

- Helps protect against cavities

##### **Warnings**

**Keep out of reach of children under 6 years of age.** If more than for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

##### **Directions**

- Adults and children 2 years of age or older, brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
- To minimize swallowing, use a pea-sized amount for children under 6.
- Supervise children's brushing until good habits are established.
- Children under 2 years of age, ask a dentist or physician.

##### **Other information**

- Twist off cap to remove foil seal.
- Do not use if safety seal is missing or broken.

##### **Inactive ingredients**

Sorbitol, Hydrated Silica, Water, Glycerin, Xylitol, Pentasodium Triphosphate, Cocamidopropyl Betaine, Titanium Dioxide, Flavor, Xanthan Gum, Sodium Methyl Cocoyl Taurate, Sucralose, Glycine, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Hydrolyzed Hyaluronic Acid.

## Questions or comments?

888-575-5700 [www.smileactives.com](http://www.smileactives.com)

Distributed by: Oral Care Products, LLC  
El Segundo, CA 90245

## PRINCIPAL DISPLAY PANEL - 170 g Tube Label

smileactives PRO™

Tartar Control  
Fluoride Toothpaste

Vanilla Mint

For Healthy Gums  
(with Amino Acids & Hyaluronic Acid)

6 OZ / 170 g

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**Inactive ingredients** Sorbitol, Hydrated Silica, Water, Glycerin, Xylitol, Pentasodium Triphosphate, Cocamidopropyl Betaine, Titanium Dioxide, Flavor, Xanthan Gum, Sodium Methyl Cocoyl Taurate, Sucralose, Glycine, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Hydrolyzed Hyaluronic Acid.

**Questions or comments?** 888-575-5700 [www.smileactives.com](http://www.smileactives.com)

**NOT TESTED ON ANIMALS**

Distributed by: Oral Care Products, LLC  
El Segundo, CA 90245  
Made in the USA of Foreign and Domestic components  
SALAB176 R1

smileactives PRO™

Tartar Control  
Fluoride Toothpaste  
Vanilla Mint  
For Healthy Gums  
(with Amino Acids & Hyaluronic Acid)  
6 OZ / 170 g

1/4" Overlap Area  
No Varnish

## SMILE ACTIVE PRO TARTAR CONTROL FLUORIDE

sodium fluoride paste

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70605-039
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Sodium Fluoride	1.5 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Hydrated Silica</b> (UNII: Y6O7T4G8P9)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Sodium Tripolyphosphate Anhydrous</b> (UNII: 9SW4PFD2FZ)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3O11KX)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>Sodium Methyl Cocoyl Taurate</b> (UNII: JVL98CG53G)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Sodium Ascorbyl Phosphate</b> (UNII: 836SJG51DR)	
<b>Glycine</b> (UNII: TE7660XO1C)	
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70605-039-22	57 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2023	
2	NDC:70605-039-96	170 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2023	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part355	04/01/2023	

**Labeler** - Guthy-Renker LLC (948861877)