

**CREST- sodium fluoride paste, dentifrice**  
**Buzz Export Services Pty., Ltd.**

*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.*

-----

**Dental Kit - Crest Toothpaste**

**Drug Facts**

**Active Ingredient**

Sodium fluoride 0.243% (0.15% w/v fluoride ion)

**Purpose**

Anticavity toothpaste

**Use**

helps protect against cavities

**Warnings**

**Keep out of reach of children under 6 yrs. of age.**

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- adults and children 2 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist
- do not swallow
- to minimize swallowing use a pea-sized amount in children under 6
- supervise children's brushing until good habits are established
- children under 2 yrs.: ask a dentist

**Inactive Ingredients**

water, sorbitol, hydrated silica, disodium pyrophosphate, xylitol, flavor, sodium hydroxide, cellulose gum, cocamidopropyl betaine, sodium laureth-2 phosphate, sodium saccharin, xanthan gum, carbomer, sucralose, polyethylene oxide, polyethylene, mica, titanium dioxide, blue 1 lake

## Questions?

1-800-959-6586

Dist. by Procter & Gamble, Cincinnati, OH 45202

## Package Labeling

### KIT 1 - CREST TOOTHPASTE 24G



**Inactive Ingredients** water, sorbitol, hydrated silica, disodium pyrophosphate, xylitol, flavor, sodium hydroxide, cellulose gum, cocamidopropyl betaine, sodium laureth-2 phosphate, sodium saccharin, xanthan gum, carbomer, sucralose, PEG-20M or PEG-23M, polyethylene, mica, titanium dioxide, blue 1 lake

Dist. by Procter & Gamble, Cincinnati, OH 45202 [www.crest.com](http://www.crest.com) ©2011 P&G

Questions? 1-800-959-6586

**Crest**  
**3D WHITE LUXE**  
FLUORIDE ANTICAVITY TOOTHPASTE

REMOVES UP TO 90% OF SURFACE STAINS IN 5 DAYS

GLAMOROUS WHITE  
VIBRANT MINT

NET WT 0.85 OZ (24 g)

EXP  
LOT

#### Drug Facts

Active ingredient	Purpose
Sodium fluoride 0.243% (0.15% w/v fluoride ion).....	Anticavity toothpaste

**Use** helps protect against cavities

#### Warnings

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

#### Directions

- adults and children 2 yrs. & older: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist
- do not swallow
- to minimize swallowing use a pea-sized amount in children under 6
- supervise children's brushing until good habits are established
- children under 2 yrs.: ask a dentist

06247441



Kit Package:



## CREST

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69491-831
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
<b>SODIUM LAURETH-2 PHOSPHATE</b> (UNII: 1I08CC3XDG)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>POLYETHYLENE OXIDE 900000</b> (UNII: 16P9295IIL)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

<b>Flavor</b>	PEPPERMINT	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69491-831-01	1 in 1 CARTON	12/23/2014	
1		24 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	12/23/2014		

**Labeler** - Buzz Export Services Pty., Ltd. (747317902)

### Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Baron Travel Product Co., Ltd.		554520509	repack(69491-831)

Revised: 5/2021

Buzz Export Services Pty., Ltd.