

**HISMILE- candy cane flavor sodium fluoride anticavity toothpaste gel**  
**HISMILE PTY LTD**

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**Candy Cane Flavor Sodium Fluoride Anticavity Toothpaste**

**Active ingredient**

Sodium Fluoride 0.243%  
(0.14 w/v fluoride ion)

**Purpose**

Anticavity

**Use**

Aids in the prevention of dental cavities

**Warnings**

Warnings

**When using this product**

- Do not swallow
- Do not use in eye area

**Keep out of reach of children under 6 years 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 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or use as directed by a dentist or doctor.
- Instruct children under 6 years of age in good brushing and rinsing habits ( to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

**Inactive ingredients**

Water

Sorbitol

Hydrated Silica

Glycerin  
Xylitol  
Disodium Phosphate  
Sucralose  
Sodium Lauroyl Sarcosinate  
Xanthan Gum  
Cellulose Gum  
Flavor  
Tetrapotassium Pyrophosphate  
Caprylyl Glycol  
Benzyl Alcohol  
Menthol  
Sodium Gluconate  
Pentylene Glycol  
Zinc Lactate  
Benzoic Acid  
Methyl Diisopropyl Propionamide  
Titanium Dioxide

**label**

CANDY CANE FLAVOR

**sodium fluoride  
anticavity toothpaste**

**CANDY CANE**

**hismile**

**Net wt. 2.1 oz (60 g)**

Distributed by:  
Hismile Pty Ltd, Burleigh  
Waters, QLD 4220 AU.

Formulated in Australia.  
Made in USA.

www.hismileteeth.com  
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PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

## Drug Facts

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PLEASE PEEL HERE



### Drug Facts (continued)

**Inactive ingredients** Water, Sorbitol, Hydrated Silica, Glycerin, Xylitol, Disodium Phosphate, Sucralose, Sodium Lauryl Sarcosinate, Xanthan Gum, Cellulose Gum, Flavor, Tetrapotassium Pyrophosphate, Caprylyl Glycol, Benzyl Alcohol, Menthol, Sodium Gluconate, Pentylene Glycol, Zinc Lactate, Benzoic Acid, Methyl Diisopropyl Propionamide, Titanium Dioxide.

### Questions or comments?

+1-302-440-3558

You may also report serious side effects to this phone number.

### TRUSTED BY DENTISTS



sugar-free



cruelty-free



no SLS & PEGs



vegan

Hismile uses the highest quality ingredients to provide a superior clean with oral health benefits. Paired with a refreshing burst of flavor, this toothpaste creates a unique smile care experience.

## HISMILE

candy cane flavor sodium fluoride anticavity toothpaste gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-327
<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:Q80VPU4080)	SODIUM FLUORIDE	0.243 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-327-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/30/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/23/2024	

**Labeler** - HISMILE PTY LTD (758083252)

## Establishment

Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(83013-327)