

**HISMILE- sodium fluoride gel**  
**HISMILE PTY LTD**

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**Cherry 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

Glycerin

Hydrated Silica

Xylitol

Sodium Phosphate

Xanthan Gum

Sodium Lauroyl Sarcosinate

Tetrapotassium Pyrophosphate

1,2-Hexanediol

Cellulose Gum

Sucralose

Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

**label**

CHERRY FLAVOR

sodium fluoride  
anticavity toothpaste

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, Glycerin, Hydrated Silica, Xylitol, Flavor, Sodium Phosphate, Xanthan Gum, Sodium Lauroyl Sarcosinate, Tetrapotassium Pyrophosphate, 1,2-Hexanediol, Cellulose Gum, Sucralose, Lauryl Glucoside, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate.

### 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

sodium fluoride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-321
<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>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-321-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/15/2024	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(83013-321)

