

**HISMILE- watermelon flavor sodium fluoride anticavity toothpaste gel**  
**Hismile Pty Ltd**

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**Watermelon Flavor Sodium Fluoride Anticavity Toothpaste**

**Active ingredient**

Sodium Fluoride 0.24% (0.14% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

aids in the prevention of dental cavities

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

**label**

Watermelon Flavor Sodium Fluoride Anticavity Toothpaste

Manufactured for:  
Hismile Pty Ltd, 225 Burleigh  
Connection Rd, Burleigh Waters,  
Queensland, Australia 4220.

Formulated in Australia.  
Made in USA.

www.hismileteeth.com  
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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.



**label**


WATERMELON FLAVOR

**sodium fluoride  
anticavity toothpaste**

Manufactured for:  
Hismile Pty Ltd, 225 Burleigh  
Connection Rd, Burleigh Waters,  
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9356 8609

PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.


**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Sodium Fluoride 0.24% (0.14% w/v fluoride ion).....	Anticavity

**Use** aids in the prevention of dental cavities

**Warnings**  
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■ 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.

Net wt. 2.1 oz (60 g)

30103119

PLEASE PEEL HERE



### **Drug Facts** (continued)

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

### **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

watermelon flavor sodium fluoride anticavity toothpaste gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-315
<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	2.4 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>CALCIUM GLYCEROPHOSPHATE</b> (UNII: XW9Z12C1C)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 83013	60 x 1 BOTTLE, RUBBER TUBES, 6.14oz		

<b>1</b>	NDC:83013-315-06	60 g in 1 BOTTLE, PUMP; Type O: Not a Combination Product	01/14/2024	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M021		01/14/2024	

**Labeler** - Hismile Pty Ltd (758083252)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Accupac, LLC		061595175	manufacture(83013-315)

Revised: 1/2024

Hismile Pty Ltd