

**HISMILE BANANA FLAVOR ANTICAVITY- sodium fluoride paste, dentifrice  
HISMILE 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.*

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**hismile BANANA FLAVOR anticavity**

***Drug Facts***

***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.

***Other information***

store in a cool, dry place.

***Inactive ingredients***

Water, Sorbitol, Hydrated Silica, Xylitol, Glycerin, Disodium Phosphate, Flavor, Sodium Lauroyl Sarcosinate, Xanthan Gum, Cellulose Gum, Tetrapotassium Pyrophosphate, Caprylyl Glycol, Benzyl Alcohol, 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.**

### **Manufactured for:**

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

Formulated in Australia.

**Made in Thailand.**

[www.hismileteeth.com](http://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.

### **Packaging**

**BANANA FLAVOR**

**sodium fluoride  
anticavity toothpaste**

Manufactured for:  
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Queensland, Australia 4220.

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9357 1906

PLEASE PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

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

Use  
Warnings  
Directions

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

**Warnings**

**When using this product** ■ do not swallow  
■ do not use in eye area

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**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. ▶

Net wt. 2.1 oz (60 g)

PLEASE PEEL HERE



**Drug Facts** (continued)

**Other information** store in a cool, dry place.

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

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## HISMILE BANANA FLAVOR ANTICAVITY

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83013-309
<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)	SODIUM FLUORIDE	2.4 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>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>METHYL DIISOPROPYL PROPIONAMIDE</b> (UNII: 6QOP5A9489)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-309-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/14/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/14/2023	

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

Revised: 6/2023

HISMILE PTY LTD