## HISMILE- sodium fluoride gel HISMILE PTY LTD

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## Cotton Candy 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

## 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.

## When using this product

Do not swallow

Do not use in eye area

#### **Directions**

Adults and children 2 years of age and older: Brush teeth thoroughly, preferrably 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 habtis (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

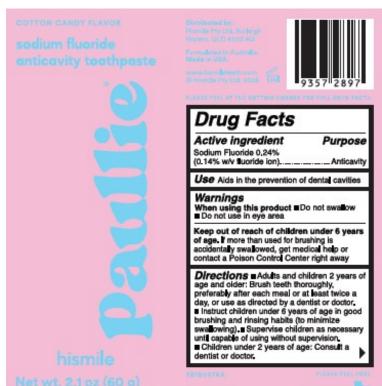
Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

D&C Red No. 33

#### Label



Cotton Candy Label.jpg

# HISMILE sodium fluoride gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:83013-323

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII: 080VPU408O)	SODIUM FLUORIDE	0.243 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
XANTHAN GUM (UNII: TTV12P4NEE)		
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)		
SODIUM GLUCONATE (UNII: R6Q3791S76)		
SORBITOL (UNII: 506T60A25R)		
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)		
XYLITOL (UNII: VCQ006KQ1E)		
WATER (UNII: 059QF0KO0R)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
1,2-HEXANEDIOL (UNII: TR046Y3K1G)		
ZINC LACTATE (UNII: 2GXR25858Y)		
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)		
SODIUM PHOSPHATE (UNII: SE337SVY37)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:83013- 323-01	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)

# Registrant - Accupac LLC (061595175)

Revised: 7/2024 HISMILE PTY LTD