

HISMILE- magically delicious flavor sodium fluoride anticavity toothpaste gel, dentifrice

Hismile Pty Ltd

Active ingredient

Sodium Fluoride 0.243%

(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.

Water

Sorbitol

Glycerin

Hydrated Silica

Xylitol

Flavor

Sodium Methyl Cocoyl Taurate

Xanthan Gum

Cellulose Gum

Sodium Lauroyl Sarcosinate

Sucralose

Tetrapotassium Pyrophosphate

Sodium Phosphate

Lauryl Glucoside

Sodium Gluconate

1,2-Hexanediol

Mica

Zinc Lactate

Methyl Diisopropyl Propionamide

Titanium Dioxide

Iron Oxides

FD&C Red No.40

Hismile Lucky Charms Magically Delicious Flavor Sodium Fluoride Anticavity Toothpaste Gel

MAGICALLY DELICIOUS™ FLAVOR

**sodium fluoride
anticavity toothpaste**

**Lucky
Charms**

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 FEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-335
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		SODIUM FLUORIDE	0.243 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
SODIUM GLUCONATE (UNII: R6Q3791S76)			
SODIUM LAURYL SARCOSINATE (UNII: 5PGH842FAU)			
1,2-HEXANEDIOL (UNII: TR046Y3K1G)			
ZINC LACTATE (UNII: 2GXR25858Y)			
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)			
XYLITOL (UNII: VCQ006KQ1E)			
XANTHAN GUM (UNII: TTV12P4NEE)			
SORBITOL (UNII: 506T60A25R)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			

IRON OXIDES (UNII: 1K09F3G675)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TETRAPOTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
MICA (UNII: V8A1AW0880)	
CELLULOSE GUM (UNII: K679OBS311)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MARSHMALLOW	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-335-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	06/01/2025	

Labeler - Hismile Pty Ltd (758083252)

Registrant - Hismile Pty Ltd (758083252)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(83013-335)

Revised: 3/2025

Hismile Pty Ltd