WATERMELON FLAVOR SODIUM FLUORIDE ANTICAVITY TOOTHPAST- sodium fluoride gel HISMILE PTY LTD

Watermelon 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

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

Glycerin

Hydrated Silica Xylitol Sorbitol Flavor Cellulose Gum 1,2-Hexanediol Sodium Phosphate

Sodium Lauroyl Sarcosinate

Tetrapotassium Pyrophosphate

Sucralose

Caprylyl Glycol

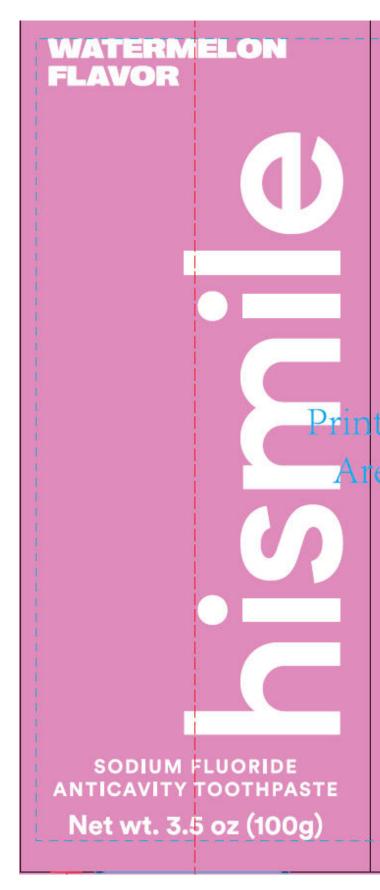
Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

Label



Drug Facts

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- hildren under 2 years of age: Consult a dentist or doctor

Inactive ingredients Water, Glycerin, Hydrated Silica, Xylitol, Sorbitol, Flavor, Cellulose Gum, 1,2-Hexanediol, Sodium Phosphate, Sodium Lauroyl Sarcosinate, Tetrapotassium Pyrophosphate, Sucralose, Caprylyl Glycol, Lauryl Glucoside, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zind Lactate,

Questions or comments?

+1-302-440-3558

You may also report serious side effects to this phone number.

Distributed by Hismile Pty Ltd, Burleigh Waters, QLD 4220 AU.

Formulated in Australia. Made in USA from globally sourced ingredients and components

WATERMELON FLAVOR SODIUM FLUORIDE ANTICAVITY TOOTHPAST

sodium fluoride gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-337	
Route of Administration	TOPICAL			

	Active Ingredient/Active Moiety			
ı	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
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE GUM (UNII: K6790BS311)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TETRAPOTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
ZINC LACTATE (UNII: 2GXR25858Y)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6Q0P5A9489)	

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-337- 10	100 g in 1 TUBE; Type 0: Not a Combination Product	10/31/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	10/31/2025	

Labeler - HISMILE PTY LTD (758083252)

Establishment			
Name	Address	ID/FEI	Business Operations

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Nutrix International, LLC.	11734	1868 manufa	acture(83013-337)

Revised: 10/2025 HISMILE PTY LTD