

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

Ice Pop Flavor Sodium Fluoride Anticavity Toothpaste

Active ingredient

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

Purpose

Anticavity

Use

Use

Aids in the prevention of dental cavities

Warnings

Warnings

When using this product

When using this product Do not swallow

Do not use

Do not use in eye area

Keep out of reach of children

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally seallowed, 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 seallowing).
- 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

Flavor

Sodium Phosphate

Xanthan Gum

Sodium Lauroyl Sarcosinate

Sucralose

Tetrapotassium Pyrophosphate

1,2-Hexanediol

Cellulose Gum

Lauryl Glucoside

Methyl Diisopropyl Propionamide

Sodium Gluconate

Zinc Lactate

FD&C Blue No. 1

label

ICE POP FLAVOR

**sodium fluoride
anticavity toothpaste**

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 PEEL AT THE BOTTOM CORNER FOR FULL DRUG FACTS.

Drug Facts

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XXXXXXXXXX

PLEASE PEEL HERE



Drug Facts (continued)

Inactive ingredients Water, Sorbitol, Glycerin, Hydrated Silica, Xylitol, Flavor, Sodium Phosphate, Xanthan Gum, Sodium Lauroyl Sarcosinate, Sucralose, Tetrapotassium Pyrophosphate, 1,2-Hexanediol, Cellulose Gum, Lauryl Glucoside, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, FD&C Blue No. 1.

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.

ICE POP FLAVOR SODIUM FLUORIDE ANTICAVITY TOOTHPAST

sodium fluoride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83013-328
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.243 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
GLYCERIN (UNII: PDC6A3C00X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ZINC LACTATE (UNII: 2GXR25858Y)	
METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83013-328-06	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	08/30/2024	

Labeler - HISMILE PTY LTD (758083252)

Establishment

Name	Address	ID/FEI	Business Operations
ACCUPAC LLC		061595175	manufacture(83013-328) , label(83013-328) , pack(83013-328)

Revised: 1/2026

HISMILE PTY LTD