

**HISMILE PINK LEMONADE SODIUM FLUORIDE ANTICAVITY TOOTHPAST-
sodium fluoride gel
Hismile Pty Ltd**

Hismile Pink Lemonade Sodium Fluoride Anticavity Toothpaste

Active ingredient

sodium fluoride 0.24%
(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 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.

Inactive ingredients

Water

Sorbitol

Glycerin
Hydrated Silica
Xylitol
Lauryl Glucoside
Sodium Phosphate
Xanthan Gum
Cellulose Gum
Sodium Lauroyl Sarcosinate
Sucralose
Tetrapotassium Pyrophosphate
1,2-Hexanediol
Methyl Diisopropyl Propionamide
Sodium Gluconate
Zinc Lactate
D&C Red No.33

label

PINK LEMONADE 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

| Active ingredient | Purpose |
|--|------------|
| Sodium Fluoride 0.24% (0.14% w/v fluoride ion)..... | Anticavity |

Use Aids in the prevention of dental cavities

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PLEASE PEEL HERE



Drug Facts (continued)

Inactive ingredients Water, Sorbitol, Glycerin, Hydrated Silica, Xylitol, Flavor, Lauryl Glucoside, Sodium Phosphate, Xanthan Gum, Cellulose Gum, Sodium Lauroyl Sarcosinate, Sucralose, Tetrapotassium Pyrophosphate, 1,2-Hexanediol, Methyl Diisopropyl Propionamide, Sodium Gluconate, Zinc Lactate, D&C Red No.33.

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.

HISMILE PINK LEMONADE SODIUM FLUORIDE ANTICAVITY TOOTHPAST

sodium fluoride gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83013-332 |
| Route of Administration | ORAL | | |

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) | |
| SORBITOL (UNII: 506T60A25R) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| LAURYL GLUCOSIDE (UNII: 76LN7P7UCU) | |
| SODIUM PHOSPHATE (UNII: SE337SVY37) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| CELLULOSE GUM (UNII: K679OBS311) | |
| POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G) | |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | |
| METHYL DIISOPROPYL PROPIONAMIDE (UNII: 6QOP5A9489) | |
| SODIUM GLUCONATE (UNII: R6Q3791S76) | |
| ZINC LACTATE (UNII: 2GXR25858Y) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | LEMON (Lemon Lime 0811578) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:83013-332-06 | 60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 01/13/2025 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M021 | 01/13/2025 | |

Labeler - Hismile Pty Ltd (758083252)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Accupac LLC | | 061595175 | manufacture(83013-332) |

Revised: 3/2025

Hismile Pty Ltd