

**COLGATE SPARKLING WHITE MINT ZING- sodium monofluorophosphate paste, dentifrice
Mission Hills S.A de C.V**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Colgate® Sparkling WH® Mint Zing 2.8ozFluoride Toothpaste

Active ingredient

Sodium monofluorophosphate 0.76% (0.14% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against cavities

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.

Directions

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.
- Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
- Children under 2 years: Ask a dentist or physician.

Inactive ingredients

glycerin, hydrated silica, water, sodium bicarbonate, PEG-12, sodium lauryl sulfate, flavor, sodium hydroxide, cellulose gum, carrageenan, sodium saccharin, calcium peroxide, titanium dioxide, FD&C green no. 3

Questions?

1-800-468-6502

www.colgate.com

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 79 g Tube Label

Colgate®

Fluoride Toothpaste

Mint Zing Paste

SPARKLING

WHITE®

with Baking Soda & Peroxide

WHITENS & PROTECTS TEETH FROM STAINS

NET WT 2.8 OZ (79 g)



The image shows the packaging for Colgate Sparkling White Mint Zing Fluoride Toothpaste. The top half is red with the Colgate logo in white and 'Fluoride Toothpaste' in smaller white text. To the right, a green and white graphic features the words 'SPARKLING WHITE' in large, bold letters, with 'Mint Zing Paste' in a smaller font above it. Below this, it says 'with Baking Soda & Peroxide' and 'WHITENS & PROTECTS TEETH FROM STAINS'. The bottom half of the packaging is white with green accents. It includes the 'Active Ingredient' section (Sodium monofluorophosphate 0.76% (0.14% w/v fluoride ion)), 'Purpose' (Anticavity), 'Inactive Ingredients' (glycerin, hydrated silica, water, sodium bicarbonate, PEG-12, sodium lauryl sulfate, flavor, sodium hydroxide, cellulose gum, carrageenan, sodium saccharin, calcium peroxide, titanium dioxide, FD&C green no. 3), 'Use' (helps protect against cavities), '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.), 'Directions' (Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician. Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing). Children under 2 years: Ask a dentist or physician.), 'Questions?' (1-800-468-6502, www.colgate.com), 'Dist. by: COLGATE-PALMOLIVE COMPANY, New York, NY 10022', and a barcode with numbers 478394 950287 5492. The Colgate logo is also present at the bottom right.

COLGATE SPARKLING WHITE MINT ZING

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65954-007
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.0 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	491.6 mg in 1 g
HYDRATED SILICA (UNII: Y607T4G8P9)	
WATER (UNII: 059QF0K00R)	

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Product Characteristics

Color	BLUE, WHITE	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65954-007-79	1 in 1 CARTON		
1		79 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/20/2011	

Labeler - Mission Hills S.A de C.V (812312122)

Revised: 1/2013

Mission Hills S.A de C.V