

**COLGATE OPTIC WHITE PROSERIES ENAMEL STRENGTH- sodium monofluorophosphate paste, dentifrice**  
**Colgate-Palmolive Company**

*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.*

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**Colgate® Optic White® ProSeries Enamel Strength**

**Active ingredient**

Sodium Monofluorophosphate 1.14% (0.19% 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 6 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 6 to 12 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing).
- Children under 6 years: Do not use unless directed by a dentist or physician.

**Inactive ingredients**

Poloxamer 105, PVP, Calcium Pyrophosphate, PEG/PPG-116/66 Copolymer, Hydrogen Peroxide (5% w/v), Silica, Flavor, Sodium Lauryl Sulfate, Tetrasodium Pyrophosphate, Sodium Saccharin, Disodium Pyrophosphate, Sucralose, BHT.

**Questions?**

**1-800-468-6502**

*Dist. by:*

**COLGATE-PALMOLIVE COMPANY**  
New York, NY 10022 U.S.A.

**PRINCIPAL DISPLAY PANEL - 59 g Tube Label**

Colgate®  
Anticavity Fluoride Toothpaste

OPTIC  
WHITE®

PRO SERIES

REMOVES  
15 YEARS  
OF STAINS\*

5%  
HYDROGEN  
PEROXIDE

ENAMEL STRENGTH

NET WT 2.1 OZ (59 g)



**COLGATE OPTIC WHITE PROSERIES ENAMEL STRENGTH**  
sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-748
Route of Administration	DENTAL		

**Active Ingredient/Active Moiety**

Active Ingredient/Active Moiety	Strength	Quantity	Form
Sodium Monofluorophosphate	1.14% (0.19% w/v fluoride ion)		

Ingredient Name		Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	1.5 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
POLOXAMER 105 (UNII: XPP85ZH76)		446 mg in 1 g		
CROSPVIDONE (UNII: 2S7830E561)				
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)				
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM ACID PYROPHOSPHATE (UNII: H5WWD9LZUD)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-748-30	1 in 1 CARTON	11/25/2021	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-748-21	1 in 1 CARTON	11/25/2021	
2		59 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	11/23/2021		

**Labeler** - Colgate-Palmolive Company (001344381)

## Establishment

Name	Address	ID/FEI	Business Operations
Mission Hills, S.A. de C.V.		812312122	ANALYSIS(35000-748) , MANUFACTURE(35000-748) , PACK(35000-748) , LABEL(35000-748)

Revised: 10/2019

Colgate-Palmolive Company