

COLGATE KIDS HALLOWEEN WICKED WATERMELON- sodium fluoride gel, 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.

GLOW in the DARK
Colgate®
Fluoride Toothpaste

Drug Facts

Active ingredient

Sodium fluoride 0.24% (0.15% 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

sorbitol, water, glycerin, hydrated silica, PEG-12, sodium lauryl sulfate, tetrasodium pyrophosphate, cocamidopropyl betaine, sodium saccharin, flavor, xanthan gum, FD&C blue no. 1, FD&C yellow no. 5

Questions?

Call toll-free **1-800-468-6502**

Dist. by:
COLGATE-PALMOLIVE COMPANY
New York, NY 10022

PRINCIPAL DISPLAY PANEL - 130 g Bottle Label

GLOW in the DARK

Colgate®

Clinically Proven Cavity and Enamel Protection

Fluoride Toothpaste

**wicked
watermelon
flavor**

NET WT 4.6 OZ (130 g) LIQUID GEL

GLOW in the DARK

Label glow brightly after exposure to natural light

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CP

www.colgate.com
Made in Mexico

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Questions? 1-800-468-6502	
Remove tab with arrows to open cap.	

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DATE CODE AREA

COLGATE KIDS HALLOWEEN WICKED WATERMELON

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-938
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	646.15 mg in 1 g
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	WATERMELON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-938-81	130 g in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/26/2011	

Labeler - Colgate-Palmolive Company (001344381)