# COLGATE ESSENTIALS WITH COCONUT OIL- sodium fluoride 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<sup>®</sup> Essentials<sup>TM</sup> with Coconut Oil

**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**

vears 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
	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, hydrated silica, PEG-12, sodium lauryl sulfate, flavor, cellulose gum, sodium saccharin, hydrogenated coconut oil, tetrasodium pyrophosphate, cocamidopropyl betaine, titanium dioxide

Questions?

1-800-468-6502

Dist. by:

**COLGATE-PALMOLIVE** COMPANY

New York, NY 10022 U.S.A.

## PRINCIPAL DISPLAY PANEL - 130 g Tube Carton

Colgate® Anticavity Fluoride Toothpaste

NEW

ESSENTIALS $^{TM}$  WITH COCONUT OIL

Daily toothpaste polishes away stains from coffee, tea and wine

NET WT 4.6 OZ (130 g) ENAMEL SAFE CLEAN MINT



Daily toothpaste polishes away stains from coffee, tea and wine

NEW

**ESSENTIA** 

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WITH COCONUT OIL

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#### **Drug Facts**

Active ingredient Purpose Sodium fluoride 0,24% (0,15% w/v fluoride ion)., \_Anticavity

Use helps protect against cavities

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.

Drug Facts (continued)

Directions

adults and children 2 brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician years of age and older use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) children 2 to 6 years

children under 2 years ask a dentist or physician

Inactive ingredients sorbitol, water, hydrated silica, PEG-12, sodium lauryl sulfate, flavor, cellulose gum, sodium saccharin, hydrogenated coconut oil, tetrasodium pyrophosphate, cocamidopropyli betaine, titanium dioxide

Questions? 1-800-468-6502



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



# Colgate

**ESSENTIALS** WITH COCONUT OIL

mint flavor for fresh breath

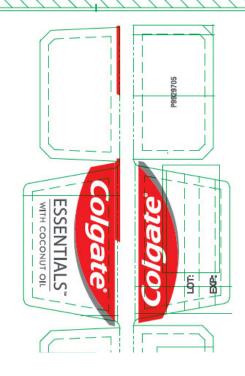


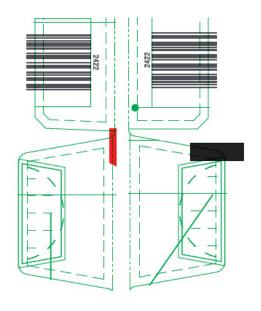
with Coconut Oil for a moisture-rich mouth feel

Daily toothpaste contains micropolishers to safely remove stains



Turning off your water while brushing your teeth can save up to 4 gallons of water each time you brush!





# COLGATE ESSENTIALS WITH COCONUT OIL

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-177
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.1 mg in 1 g	

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL (UNII: 506T60A25R)				
WATER (UNII: 059QF0KO0R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS311)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
HYDROGENATED COCONUT OIL (UNII: JY8 10 XM10 M)				
SODIUM PYROPHO SPHATE (UNII: O352864B8Z)				
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	

#### **Contains**

]	Packaging			
#	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:35000-177-46	1 in 1 CARTON	11/28/2018	
1		130 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	11/28/2018	

# Labeler - Colgate-Palmolive Company (001344381)

Establishment				
Name	Address	ID/FEI	Business Operations	
Colgate-Palmolive		785047999	MANUFACTURE(35000-177)	

Revised: 12/2019 Colgate-Palmolive Company