#### COLGATE KIDS TROLLS ALCOHOL FREE ANTI-CAVITY SPARKLE TIME BUBBLE FRUIT- sodium fluoride rinse 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> Kids Trolls Alcohol Free Anti-Cavity Sparkle Time<sup>™</sup> Bubble Fruit<sup>®</sup> Drug Facts

## Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

## Purpose

Anticavity

#### Use

aids in the prevention of dental cavities

## Warnings

**Keep out of reach of children.** If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

## Directions

#### Adults and children 6 years of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

## Children under 6 years of age: consult a dentist or doctor

## Other information

Store at controlled room temperature 68 – 77° F (20 – 25°C)

### Inactive ingredients

water, glycerin, propylene glycol, sorbitol, poloxamer 338, poloxamer 407, flavor, PEG-40 castor oil, phosphoric acid, sodium saccharin, disodium phosphate, potassium sorbate, cetylpyridinium chloride, sucralose, D&C red no. 33, FD&C green no. 3

#### Questions?

1-800-468-6502

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

#### PRINCIPAL DISPLAY PANEL - 250 mL Bottle Label

NEW

ALCOHOL FREE Colgate<sup>®</sup>

Anticavity Fluoride Rinse

Kids

DREAMWORKS Trolls

- StrengthensEnamel
- Protects from Cavities
- Cleans the Whole Mouth\*

P9913559

8.4 FL OZ (250mL)

Sparkle Time<sup>™</sup> Bubble Fruit<sup>®</sup> IMPORTANT: Read directions for proper use



## COLGATE KIDS TROLLS ALCOHOL FREE ANTI-CAVITY SPARKLE TIME BUBBLE FRUIT

sodium fluoride rinse

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:35	DC:35000-383	
Route of Administration	DENTAL					
Active Ingredient/Active Moiety						
Ingredient Name			<b>Basis of Stre</b>	ngth	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)			FLUORIDE ION	0	0.1 mg in 1 mL	
Inactive Ingredients						

	Ingredient	Name	Strength
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC	9Q167V3)		
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 338 (UNII: F75JV2T	505)		
POLOXAMER 407 (UNII: TUF2IVW	V3M2)		
POLYOXYL 40 HYDROGENATE	D CASTOR OIL (UNII	: 7YC686GQ8F)	
PHOSPHORIC ACID (UNII: E4GA8	8884NN)		
SACCHARIN SODIUM (UNII: SB8	ZUX40TY)		
SODIUM PHOSPHATE, DIBASIC	, ANHYDROUS (UNI	I: 22ADO53M6F)	
POTASSIUM SORBATE (UNII: 1V	/PU26JZZ4)		
	(UNII: D9OM4SK49P)		
LEVOMENTHOL (UNII: BZ1R15M	TK7)		
SUCRALOSE (UNII: 96K6UQ3ZD4	-)		
D&C RED NO. 33 (UNII: 9DBA0S	BBOL)		
FD&C GREEN NO. 3 (UNII: 3P30	NR601S)		
Product Characteristics	5		
	5 PURPLE	Score	
Color	-	Score Size	
Color Shape	-	Size	
<b>Product Characteristics</b> Color Shape Flavor Contains	PURPLE		
Color Shape Flavor	PURPLE	Size	
Color Shape Flavor	PURPLE	Size	

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-383- 84	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2019	12/30/2024
2	NDC:35000-383- 16	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2016	12/30/2024

# Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part355	08/05/2016	12/30/2024

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Labeler - Colgate-Palmolive Company (001344381)
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Revised: 1/2023