ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol liquid WALMART INC. (see also Equate)

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.

Kalaya Breath Refresh Antiseptic Oral Rinse-updated label for NDC

Active ingredient

Eucalyptol (0.092%)

Menthol (0.042%)

Methyl Salicylate (0.060%)

Thymol (0.064%)

Purposes

Antiplaque/antigingivitis

Uses

helps prevent and reduce

- plaque
- gingivitis

Warning

Do not use

in children under 12 years of age.

Stop use and ask a dentist

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away

Other information

• store at room temperature

- cold weather may cloud this product. Its antiseptic properties are not affected.
- this rinse is not intended to replace brushing or flossing

Directions

- adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse.
- children 6 years to under 12 years of age: supervise use
- children under 6 years of age: do not use

Inactive ingredients

water, alcohol (21.6% v/v), sorbitol, poloxamer 407, flavor, sodium benzoate, benzoic acid, sodium saccharin, green #3

Questions or comments

1-888-287-1915

Principal display panel

Compare to Listerine® Cool Mint® active ingredient

Antiseptic Mouthwash

Eucalyptol (0.092%)

Menthol (0.042%)

Methyl salicylate (0.060%)

Thymol (0.064%)

Antiplaque/antigingivitis

- Kills germs that cause plaque, gingivitis, bad breath
- Help to control and prevent plaque that leads to gingivitis

Blue Mint

L (QT PT FL OZ)

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Listerine® Cool Mint®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY: Walmart Inc.,

Bentonville, AR 72716

Package label



EQUATE Antiseptic Mouthwash

ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:79903-151 **Route of Administration ORAL**

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL	
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALCOHOL (UNII: 3K9958V90M)			
SORBITOL (UNII: 506T60A25R)			
POLOXAMER 407 (UNII: TUF2IVW3M2)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903- 151-75	1.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2022	
2	NDC:79903- 151-50	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2022	
3	NDC:79903- 151-99	2 in 1 PACKAGE	12/30/2022	
3		1.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	12/30/2022		

Labeler - WALMART INC. (see also Equate) (051957769)

Revised: 1/2023 WALMART INC. (see also Equate)