MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Kroger

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.

Herbal Mint Antiseptic Mouthwash D01.000/D01AA rev 1

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis

Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Do not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

gingivitis, bleeding, or redness persists for more than 2 weeks

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 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth twice a day for 30 seconds 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

• this rinse is not intended to replace brushing or flossing

Other information

cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59°to 86°F)

Inactive ingredients

water, alcohol (21.6% v/v), sorbitol, capryl/capramidopropyl betaine, flavor, benzoic acid, Stevia rebaudiana leaf extract, sodium benzoate

Questions or Comments?

Call roll free 1-800-632-6900

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

For More Proudct Information, Scan UpcUsing Your Kroger App or Call 800-632-6900

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Breath & Gum Cleanser

ANTIGINGIVITIS/ANTIPLAQUE MOUTHWASH

WITH ESSENTIAL OILS

HERBAL MINT

fights bad breath

helps prevent plaque & gingivitis

imrproves oral hygiene

for refreshing oral care
NO ARTIFICIAL SWEETNERS OR DYES
NO POLYETHYLENE GLYCOL
33.8 FL OZ (1.05 QT) 1L



MOUTH RINSE

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59450-901
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Eucalyptol (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	Eucalyptol	.92 mg in 1 mL		
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	.42 mg in 1 mL		
Methyl salicylate (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Methyl salicylate	.60 mg in 1 mL		
Thymol (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	Thymol	.64 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
water (UNII: 059QF0KO0R)			
alcohol (UNII: 3K9958V90M)			

sorbitol (UNII: 506T60A25R)		
CAPRYL/CAPRAMIDOPROPYL BETAINE (UNII: 231H3ZT9NE)		
benzoic acid (UNII: 8SKN0B0MIM)		
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)		
sodium benzoate (UNII: OJ245FE5EU)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:59450- 901-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/21/2023		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/21/2023	
Tinai			

Labeler - Kroger (006999528)

Registrant - Vi Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(59450-901)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(59450-901)

Revised: 3/2023 Kroger