

ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyol salicylate, thymol mouthwash
TOPCO ASSOCIATES, LLC

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.

Drug Facts 072.000/072AL rev 2

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 for 30 seconds then spit out; do not swallow

children under 12 years of age - consult a dentist or doctor

- 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° - 77°F)

Inactive ingredients

water, alcohol 21.6%, sorbitol solution, flavoring, poloxamer 407, benzoic acid, sodium saccharin, sodium citrate, D+C yellow no. 10, FD+C green no.3

claims

The ADA Council on Scientific Affairs Acceptance of Top Care Spring Mint Antiseptic Mouth Rinse is based on it finding that the product is

effective in helping to prevent and reduce gingivitis and plaque above the gumline, when used as directed.

This product is not manufactured or distributed by Johnson + Johnson Healthcare Products, distributor of Listerine

DSP-TN-15000, DSP-MO-34, SDS-TN-15012

Adverse reaction

DISTRIBUTED BY TOPCO ASSOCIATES LLC

7711 GROSS POINT ROAD, SKOKIE, IL 60077

QUESTIONS? 1-888-423-0139 topcare@topco.com

072.002/072AL

principal display panel

TOP CARE

Sealed With Pringed Neckband For Your Protection

SPRING MINT

Antiseptic

Mouth

Rinse

ADA

Accepted

American

Dental

Association

Kills Germs that Cause

Bad Breath,

Plaque, & the

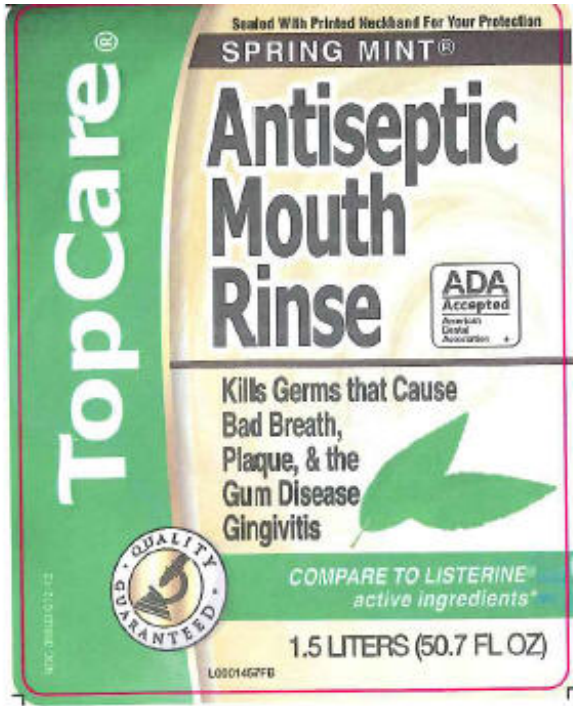
Gum Disease

Gingivitis

COMPARE TO LISTERINE

active ingredients

1.5 LITERS (50.7 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyol salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-072
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	0.60 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)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/1995	
2	NDC:36800-072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/1995	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/07/1995	

Labeler - TOPCO ASSOCIATES, LLC (006935977)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(36800-072)

Revised: 4/2020

TOPCO ASSOCIATES, LLC