ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Old East Main Co

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.

Dye-Free Antiseptic Mint Mouthrinse 567.000/567AA

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Active ingredients

Eucalyptol 0.092% Menthol 0.042% Methyl salicylate 0.060% Thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use

help 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, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, flavor

Since 1903 Rexall® is a registered trademark of Rexall Sundown, Inc.

100% SATISFACTION GUARANTEED!

If you're not satisfied with this product for any reason, please call us so we can make you 100% satisfied.

(888)309-9030

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Principal display panel

Since 1903

Rexall

Antiseptic Mint

Mouthwash

Antigingivitis/Antiplaque

Dye-Free

• Kills 99.9% of germs commonly associated with gingivitis

MINT

1 L (33.8 FL OZ)



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

| Product Information | | | | | |
|--|-----------------|----------------------------------|----------------------|----|--------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) NDC:55910-747 | | | 55910-747 |
| Route of Administration | ORAL | | | | |
| | | | | | |
| Active Ingredient/Active | Moiety | | | | |
| Ingre | dient 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 - METHYL SALICYLIC ACID - METHYL SALICYLICACID - METHYL SAL | | | | | 0.60 mg in 1 mL |
| THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) THYM | | | THYMOL | | 0.64 mg in 1 mL |
| | | | | | |
| Inactive Ingredients | | | | | |
| | Ingredient Name | | | St | trength |
| WATER (UNII: 059QF0K00R) | | | | | |

ALCOHOL (UNII: 3K9958V90M)

| fin | al | | | | |
|-----------------------|-------------------------|--|-----|-------------------------|-----------------------|
| | C monograph no | part356 | 10/ | /04/2021 | |
| | Marketing Category | Application Number or Monograph Citation | Ν | Aarketing Start Date | Marketing End Date |
| Marketing Information | | | | | |
| - | | | | | |
| | | | | | |
| 1 | | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | - | 10/04/2021 | |
| # | ltem Code | Package Description | | Marketing Start Date | Marketing End Date |
| Pa | ackaging | | | | |
| | | | | | |
| 50 | | | | | |
| | | UM (UNII: SB8ZUX40TY) TE (UNII: OJ245FE5EU) | | | |
| | | | | | |
| | | (UNII: TUF2IVW3M2) | | | |
| | DRBITOL (UNII: 5 | 00100A25N) | | | |

Labeler - Old East Main Co (068331990)

Registrant - Vi-Jon, LLC (790752542)

| Establishment | | | | |
|---------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Vi-Jon, LLC | | 790752542 | manufacture(55910-747) | |

| Establishment | | | | |
|---------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Vi-Jon, LLC | | 088520668 | manufacture(55910-747) | |

Revised: 7/2023

Old East Main Co