

**ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Publix Super Markets, Inc.**

**Publix 664.003/664AT rev 2-664AU
Blue Mint Antiseptic Mouthrinse**

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, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD&C green no.3

Tamper Evident Statement

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine .

Adverse Reactions

Distributed by: Publix Super Markets, Inc.,

3300 Publix Corporate Parkway

Lakeland, FL 33811 publix.com

PUBLIX GUARANTEE:

COMPLETE SATISFACTION OR YOUR MONEY BACK

Publix

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

principal display panel

P

cool

fresh

ANTIGINGIVITIS/ANTIPLAQUE

MOUTH RINSE

Kills germs that cause :

- Bad breath
- Plaque
- The gum disease gingivitis

ADA Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

*Compare to the active ingredients of Listerine®

33.8 FL OZ (1.05 QT) 1 L

cool fresh

ANTINGINGIVITIS/ANTIPLAQUE MOUTHRINSE

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- Plaque
- The gum disease gingivitis

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Helps reduce plaque
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33.8 FL OZ (1.05 QT) 1 L

L0001713FD

| | |
|--|---|
| Drug Facts | |
| Active Ingredients | Purpose |
| Eucalyptol 0.092%, Menthol 0.042% | Antigingivitis, Antiplaque |
| Methyl salicylate 0.069%, Thymol 0.064% | Antigingivitis, Antiplaque |
| Use helps control plaque that leads to gingivitis | |
| Warnings | |
| 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 | vigorous swish 20 mL (2/3 fl oz or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow |
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| Inactive Ingredients water, alcohol 21.6%, sorbitol solution, flavor, polyoxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD&C green no. 3 | |

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3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33611 publix.com

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COMPLETE SATISFACTION OR YOUR MONEY BACK

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DSP-TN-15000
DSP-MO-34
SDS-TN-15012
L0001713BF

ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:56062-664 |
| 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) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:56062-664-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/1994 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | 505G(a)(3) | 03/30/1994 | |

Labeler - Publix Super Markets, Inc. (006922009)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|------------------------|
| Nice-Pak Products, LLC | | 119091514 | manufacture(56062-664) |