MARCS SPRING MINT- eucalyptol, menthol, methyl salicylate, thymol liquid APOLLO HEALTH AND BEAUTY CARE

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

ACTIVE INGREDIENTS

EUCALYPTOL 0.092%, MENTHOL 0.042%, METHYL SALICYLATE 0.060%, THYMOL 0.064%

PURPOSE

ANTIPLAQUE/ANTIGINGIVITIS

USES

TO HELP REDUCE AND PREVENT PLAQUE AND GINGIVITIS

WARNINGS

DO NOT USE FOR CHILDREN UNDER 12 YEARS OF AGE

KEEP OUT OF REACH OF CHILDREN

IF MORE THAN USED FOR RINSING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY (1-800-222-1222)

DIRECTIONS

RINSE FULL STRENGTH FOR 30 SECONDS WITH 20 ML (2/3 FLUID OUNCE OR 4 TEASPOONFULS) MORNING AND NIGHT. DO NOT SWALLOW

OTHER INFORMATION

STORE AT ROOM TEMPERATURE. COLD WEATHER MAY CLOUD THIS PRODUCT. ITS ANTISEPTIC PROPERTIES ARE NOT AFFECTED

INACTIVE INGREDIENTS

WATER (AQUA), ALCOHOL (21.6%), SORBITOL SOLUTION, FLAVOR, POLOXAMER 407, BENZOIC ACID, SODIUM SACCHARIN, SODIUM BENZOATE, YELLOW 10 (CI 47005), GREEN 3 (CI 42063)

LABEL COPY



Drug Facts

Active ingredients Eucalyptol 0.092%

Antiplaque/Antigingiviti:

Menthol 0.042% Methyl Salkylate 0,060% Thymol 0.064%

Uses ■ To help reduce and prevent plaque and ginglvitis

Warnings

Do not use = for children under 12 years of age.

Keep out of reach of children.

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

Directions = Rinse full strength for 30 seconds with 20 mL (2/3 fluid ounce or 4 teaspoonfuls) morning and night.

Do not swallow.

Other Information = Store at room temperature. = Cold weather may doud this product. Its antiseptic properties are not affected.

Inactive ingredients: Water (Aqua), Akohol (21.6%), Sorbitol Solution, Flavor, Poloxamer 407, Benzolc Add, Sodium Saccharin, Sodium Benzoate, Yellow 10 (Cl 47005), Green 3 (Cl 42053),

Do not use if printed band around cap is broken or missing. To open: Squeeze smooth areas on cap and turn. To close: Turn cap until it locks.

Distributed by: Marc Glassman, Inc. West 130th Street Cleveland, OH 44130 Made in Canada

06-19525



Purpose



MARCS SPRING MINT

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-558

Route of Administration ORAL

Active Ingredient/Active Moiety Basis of Strength Ingredient Name Strength EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK) **EUCALYPTOL** 0.92 mg in 1 mLMENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL $0.42 \ mg \ in \ 1 \ mL$ METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ) METHYL SALICYLATE 0.6 mg in 1 mL THYMOL (UNII: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E) 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: 8 SKN0 B0 MIM) | | | |
| SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY) | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | |
| 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:63148-558-51 | 1500 mL in 1 BOTTLE, PLASTIC | | |

| Marketing Information | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph not final | part356 | 02/13/2014 | | | |
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Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

| Establishment | | | | | |
|-------------------------------|---------|-----------|------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| APOLLO HEALTH AND BEAUTY CARE | | 201901209 | manufacture(63148-558) | | |

Revised: 2/2014 APOLLO HEALTH AND BEAUTY CARE