

ADVANCED HAND SANITIZER- alcohol gel
Safe Palms, 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

Active Ingredients

Ethyl Alcohol 70%

Purpose

Antibacterial

Use

For rinse-free hand sanitizing to remove 99.9% bacteria on skin

Warnings

Flammable. Keep away from fire or flame. For external use only.

When using this product

Do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if irritation and redness develop and persist.

Keep out of reach of children.

If swallowed, get medical help promptly.

Directions

Wet hands thoroughly with product and allow to dry without wiping.

Other Information

Store under 105°F

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Glycerin, Lemon Essential Oil, Purified Water, Tocopheryl Acetate (Vitamin E)

**Safe +
Palms**

**ADVANCED
HAND SANITIZER**

70% Alcohol

Gel Formula

Kills 99.99% of Germs
and Bacteria

Hypoallergenic
Patented Formula

MADE IN
USA

LEMON SCENTED

16 fl oz (480ml) • safepalms.com

die line
stay within for print safe area

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DISTRIBUTED BY: Safe Palms, LLC
Chicago, IL 60654

www.safepalms.com

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ADVANCED HAND SANITIZER

alcohol gel

Product Information

| | | | | |
|---|-------------------|---|-----------------------------|----------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:90 117-102 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | ALCOHOL | 70 mL in 100 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | | | | |
| BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E) | | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | | | | |
| Lemon Oil (UNII: I9GRO824LL) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:90 117-102-01 | 60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| 2 | NDC:90 117-102-02 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| 3 | NDC:90 117-102-03 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| 4 | NDC:90 117-102-04 | 480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| 5 | NDC:90 117-102-05 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| 6 | NDC:90 117-102-06 | 1892 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| 7 | NDC:90 117-102-07 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/25/2020 | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part333A | 08/25/2020 | |
| Labeler - Safe Palms, LLC (117609055) | | | | |
| Establishment | | | | |
| Name | | Address | ID/FEI | Business Operations |

Music City Laboratories, Llc

117409349

MANUFACTURE(90 117-102)

Revised: 8/2020

Safe Palms, LLC