

32OZ HAND SANITIZER GEL LEMONGRASS EVERCARE LABS- 32oz/946.35ml gel
lemongrass - evercare labs gel
SunBeam Laboratories 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.

32oz/946.35ml Gel Lemongrass- EverCare Labs

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

A) Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

B) Isopropyl Alcohol (1.00% v/v).

C) Carbomer (0.30% v/v).

D) Triethanolamine (0.15% v/v)

E) Aloe Vera (0.01%v/v)

F) Lemongrass (0.01%v/v)

Sterile distilled water or boiled cold water. The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Isopropyl Alcohol, Carbomer, Triethanolamine, Aloe Vera, Lemongrass, Sterile distilled water or boiled cold water.

Package Label - Principal Display Panel

KILLS
BACTERIA
& VIRUSES

EverCare
LABORATORIES

**HAND
SANITIZER
GEL**

70% Alcohol Antimicrobial

Lemongrass

**MADE IN THE
USA**

32 oz.

701575751297

| Drug Facts : | |
|---|----------------|
| Active Ingredient | Purpose |
| 70% Ethyl Alcohol (v/vT) | Antimicrobial |
| Uses: Recommended for repeated use. Hand sanitizer to help reduce bacteria on the skin. | |
| Directions: Place enough product in your palm to thoroughly cover your hands and rub together until dry. Children under 6 years should be supervised when using this product to avoid swallowing. | |
| Other Information: Store at temperature below 110F (43C). May discolor certain fabrics or surfaces | |
| Warning: For external use only. If swallowed, get medical help or contact a poison Control Center right away Avoid contact with eyes. If product gets into eyes, rinse thoroughly with water. Do not use on open wounds. Flammable. Keep away from sources of heat, fire, or flame. Stop and ask a doctor if irritation or redness develops and lasts. | |
| Inactive Ingredients: Isopropyl, Carbomer Triethanolamine, Aloe Vera, Water, Lemongrass Oil | |

ALOE VERA
LABORATORY TESTED

Manufactured By :
EverCare Laboratories
www.evercarelab.com

946.35 mL NDC: 75321-7032-5

32OZ HAND SANITIZER GEL LEMONGRASS EVERCARE LABS

32oz/946.35ml gel lemongrass - evercare labs gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75321-7032 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|------------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 662.45 mL in 946.35 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|------------------------|
| EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW) | 0.09 mL in 946.35 mL |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | 9.46 mL in 946.35 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 2.84 mL in 946.35 mL |
| WATER (UNII: 059QF0KO0R) | 269.99 mL in 946.35 mL |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 0.09 mL in 946.35 mL |
| TROLAMINE (UNII: 9O3K93S3TK) | 1.42 mL in 946.35 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:75321-7032-5 | 946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - SunBeam Laboratories LLC (105139335)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|----------------|---------------|----------------------------|
| SunBeam Laboratories LLC | | 105139335 | manufacture(75321-7032) |

Revised: 11/2020

SunBeam Laboratories LLC