

HAND SANITIZER GEL- alcohol 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.

2oz Hand Sani Gel -SL

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. IsopropylAlcohol (1.00% v/v).
- c. Carbomer (0.30% v/v).
- d. Triethanolamine (0.15% v/v)
- e. 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, purified water USP

Package Label - Principal Display Panel



The image shows the principal display panel of a hand sanitizer gel package. The background is light blue with a white curved bottom edge. In the top left, a red curved banner contains the text "KILLS BACTERIA & VIRUSES". The top right features the Sunbeam Laboratories logo, which consists of a stylized sunburst icon above the text "SUNBEAM LABORATORIES". The center of the label is dominated by the product name "HAND SANITIZER GEL" in large, bold, blue letters with a white outline and a drop shadow effect. Below this, a green banner reads "70% Alcohol Antimicrobial". In the bottom right corner, there is a circular "MADE IN THE USA" logo with an American flag design and a barcode with the number "701575751136". On the left side, there is a "Drug Facts" table and several smaller icons: "ALOE VERA" and "LABORATORY TESTED". At the bottom left, it says "Manufactured By: Sunbeam Laboratories" and "2 oz." is printed in large white letters on the blue background.

| 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: Water, Isopropyl, Carbomer, Triethanolamine, Aloe Vera | |

59.15 mL NDC: 75321-2002-2

HAND SANITIZER GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75321-2002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 41.4 mL in 59.15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------------------|
| TROLAMINE (UNII: 9O3K93S3TK) | 0.09 mL in 59.15 mL |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | 0.59 mL in 59.15 mL |
| CARBOMER 940 (UNII: 4Q93RCW27E) | 0.18 mL in 59.15 mL |
| WATER (UNII: 059QF0K00R) | 16.88 mL in 59.15 mL |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | 0.01 mL in 59.15 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:75321-2002-2 | 59.15 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(75321-2002) |