

**HAND SANITIZER- 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.*

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**16oz Gel Hand Sani -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. Isopropyl Alcohol (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, Sterile distilled water or boiled cold water

### Package Label - Principal Display Panel

The image shows the principal display panel of a hand sanitizer gel package. The label is primarily blue and white with a red accent at the top left. It features the Sunbeam Laboratories logo in the top right, which consists of a stylized sunburst icon above the text 'SUNBEAM LABORATORIES'. The central text reads 'HAND SANITIZER GEL' in large, bold, blue letters with a white outline and a drop shadow. Below this, a green banner states '70% Alcohol Antimicrobial'. In the top left, a red curved banner says 'KILLS BACTERIA & VIRUSES'. A 'Drug Facts' table is located on the left side, containing information about the active ingredient (70% Ethyl Alcohol), uses, directions, other information, warning, and inactive ingredients. A circular seal on the right side of the label says 'MADE IN THE USA' with an American flag motif. At the bottom left, there are two circular logos: 'ALOE VERA' and 'LABORATORY TESTED'. The bottom of the label features the text 'Manufactured By: Sunbeam Laboratories' and '16 oz.' in large white letters. A barcode is located in the bottom right corner with the number 701575751167 below it.

Drug Facts :	
<b>Active Ingredient</b>	<b>Purpose</b>
70% Ethyl Alcohol (v/vT)	Antimicrobial
<b>Uses:</b> Recommended for repeated use. Hand sanitizer to help reduce bacteria on the skin.	
<b>Directions:</b> 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.	
<b>Other Information:</b> Store at temperature below 110F (43C). May discolor certain fabrics or surfaces	
<b>Warning:</b> 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.	
<b>Inactive Ingredients:</b> Water, Isopropyl, Carbomer, Triethanolamine, Aloe Vera	

473.18 mL NDC: 75321-2016-2

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75321-2016
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	331.22 mL in 473.18 mL

### Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.71 mL in 473.18 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 mL in 473.18 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	4.73 mL in 473.18 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1.42 mL in 473.18 mL
WATER (UNII: 059QF0KO0R)	135.04 mL in 473.18 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-2016-2	473.18 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(75321-2016)

Revised: 7/2020

SunBeam Laboratories LLC