

HAND SANITIZER- alcohol spray
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.

16oz Spray 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) (80%, 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 (0.50% v/v).
- c. Aloe Vera (0.01% v/v).
- d. 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 80% 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.

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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, Aloe Vera, Sterile distilled water or boiled cold water.

Package Label - Principal Display Panel

The image shows the principal display panel of a hand sanitizer package. The background is light blue with a white circular glow behind the product name. At the top left, a red curved banner contains the text 'KILLS BACTERIA & VIRUSES'. In the top right corner is the Sunbeam Laboratories logo, which consists of a stylized sunburst icon above the text 'SUNBEAM LABORATORIES'. The product name 'HAND SANITIZER' is written in large, bold, blue and white letters with a red outline. Below the name, a green banner reads '80% Alcohol Antimicrobial'. On the right side, there is a circular 'MADE IN THE USA' seal with an American flag design. At the bottom left, there are two circular icons: one for 'ALOE VERA' and another for 'LABORATORY TESTED'. Below these icons, it says 'Manufactured By: Sunbeam Laboratories'. At the bottom center, the volume '16 oz.' is printed in large white letters. At the bottom right, there is a barcode with the number '701575751235' printed below it. On the left side, there is a 'Drug Facts' box with the following text: 'Drug Facts: Active Ingredient: 80% Ethyl Alcohol (v/vT) Purpose: 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, Aloe Vera.'

473.18 mL NDC: 75321-1016-2

HAND SANITIZER

alcohol spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75321-10 16

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	378.56 mL in 473.18 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	2.37 mL in 473.18 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 mL in 473.18 mL
WATER (UNII: 059QF0KO0R)	92.22 mL in 473.18 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-10 16-2	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(75321-10 16)

Revised: 7/2020

SunBeam Laboratories LLC