

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.

128oz 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 background is light blue with a white and green curved design at the bottom. In the top left, a red banner says "KILLS BACTERIA & VIRUSES". The Sunbeam Laboratories logo is in the top right. The central text reads "HAND SANITIZER GEL" in large, bold, blue letters with a white outline. Below this, a green banner says "70% Alcohol Antimicrobial". In the bottom right, there is a barcode with the number 701575751198. The bottom left features two circular logos: "ALOE VERA" and "LABORATORY TESTED". The text "Manufactured By: Sunbeam Laboratories" and "128 oz." is at the bottom.

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	

3785.41 mL NDC: 75321-2128-2

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75321-2128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2649.79 mL in 3785.41 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	5.68 mL in 3785.41 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.38 mL in 3785.41 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	37.85 mL in 3785.41 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	11.36 mL in 3785.41 mL
WATER (UNII: 059QF0KO0R)	1080.36 mL in 3785.41 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-2128-2	3785.41 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(75321-2128)

Revised: 7/2020

SunBeam Laboratories LLC