

**HAND SANITIZER- alcohol liquid**  
**SuGanit Bio-Renewables 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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**Antiseptic Hand Sanitizer (70%)**

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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% 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 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.

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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

glycerin, hydrogen peroxide, propylene glycol, Polyacrylate Crosspolymer-6, Polysorbate 20, sucros octaacetate, lavender oil, wheat germ oil, tacopheryl acetate, distilled water USP

### Package Label - Principal Display Panel

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE) [2 FL OZ.]



PRINCIPAL DISPLAY PANEL (BACK OF PACKAGE) [2 FL OZ.]

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 70% v/v	Antiseptic
<b>Use(s)</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. <b>Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• In children less than 2 months of age.</li> <li>• On open skin wounds.</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other Information</b>	
<ul style="list-style-type: none"> <li>• Store between 15°C, 30°C (59°F, 86°F).</li> <li>• Avoid freezing and excessive heat above 40°C (104°F).</li> </ul>	
<b>Inactive ingredients</b> water, glycerin, Vitamin E, hydrogen peroxide, polysorbate 20, moisturizing oil, fragrance, thickeners.	
Barcode 77316*17101	Made in USA SuGarit Bio-Renewables LLC 377 Industrial Park Rd, VA Jackson, VA, 22842

2 FL OZ. NDC: 77316-171-01

## HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77316-171
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)		0.033 mL in 100 mL	
	GLYCERIN (UNII: PDC6A3C0OX)		1.4 mL in 100 mL	
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)		1.4 mL in 100 mL	
	WATER (UNII: 059QF0K00R)			
	WHEAT GERM OIL (UNII: 14C97E680P)		0.067 mL in 100 mL	
	LAVENDER OIL (UNII: ZBP1YXW0H8)		0.1 mL in 100 mL	
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		0.75 mL in 100 mL	
	AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)		0.5 mL in 100 mL	
	POLYSORBATE 20 (UNII: 7T1F30V5YH)		0.3 mL in 100 mL	
	SUCROSE OCTAACETATE (UNII: 07V591057T)		0.14 mL in 100 mL	
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77316-171-01	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

**Labeler** - SuGanit Bio-Renewables LLC (117489749)

**Registrant** - SuGanit Bio-Renewables LLC (117489749)

### Establishment

Name	Address	ID/FEI	Business Operations
SuGanit Bio-Renewables LLC		117489749	manufacture(77316-171)