

**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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**SuVitae 70% Hand Sanitizer with moisturizing oils (8 Oz.)**

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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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

glycerin, hydrogen peroxide, Vitamin E, fragrance, thickener, moisturizing oils, distilled water

### Package Label - Principal Display Panel

PRINCIPAL DISPLAY PANEL



DRUG FACTS LABEL

<b>Drug Facts</b>	
<b>Active ingredient</b> Ethyl Alcohol 70% v/v	<b>Purpose</b> 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. Flammable. Keep away from heat or flame.	
<b>Do not use</b> • In children less than 2 months of age. • On open skin wounds.	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. There may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15°C - 30°C (59°F - 86°F). • Avoid freezing and excessive heat above 40°C (104°F).	
<b>Inactive ingredients</b> water, glycerin, Vitamin E, hydrogen peroxide, polysorbate 20, moisturizing oil, fragrance, thickener.	

Barcode  
77316-171-02

Made in USA

SuGanit Bio-Renewables LLC  
377 Industrial Park Rd, Mt Jackson, VA, 22842

8 Oz. (236 mL) NDC: 77316-171-02

## 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>		
	GLYCERIN (UNII: PDC6A3C0OX)	1.4 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		
	LAVENDER OIL (UNII: ZBP1YXW0H8)	0.1 mL in 100 mL		
	WHEAT GERM OIL (UNII: 14C97E680P)	0.067 mL in 100 mL		
	ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.033 mL in 100 mL		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.75 mL in 100 mL		
	POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.3 mL in 100 mL		
	SUCROSE OCTAACETATE (UNII: 07V591057T)	0.14 mL in 100 mL		
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)	1.4 mL in 100 mL		
	WATER (UNII: 059QF0KO0R)			
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77316-171-02	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/15/2020		

**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)