

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.

SuVita 70% Hand Sanitizer-- no essential 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.

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

hydrogen peroxide, glycerin, thickeners, distilled water

Package Label - Principal Display Panel

PRINCIPAL DISPLAY PANEL

DRUG FACTS LABEL

Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
Use(s)	
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. There may be signs of a allergic 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°C - 30°C (59°F - 86°F). • Avoid freezing and excessive heat above 40°C (104°F).	
Inactive ingredients water, glycerin, Vitamin E, hydrogen peroxide, thickeners.	

Barcode
77316-172-02

Made in USA

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

8 Oz (236 mL) NDC: 77316-172-02

HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77316-172
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	70 mL in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				0.75 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)				
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)				0.5 mL in 100 mL
SUCROSE OCTAACETATE (UNII: 07V591057T)				0.14 mL in 100 mL
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77316-172-02	00 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/15/2020	
Marketing Information				
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)

Establishment

Name	Address	ID/FEI	Business Operations
Suganit Bio-Renewables LLC		117489749	manufacture(77316-172)

Revised: 5/2020

SuGanit Bio-Renewables LLC