

# **BONAFIDE INNOVATIONS LIQUID HAND SANITIZER- alcohol liquid**

## **Bonafide Innovations LLC**

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### **Bonafide Innovations Liquid Hand Sanitizer Gallon Jug**

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 75% 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

aloe vera, fragrance, glycerin, isopropyl alcohol, panthenol, propylene glycol, purified water USP, tocoheryl acetate

### Package Label - Principal Display Panel



**BONAFIDE INNOVATIONS LIQUID HAND SANITIZER**

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71849-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2.38 kg in 3.79 L

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.00038 kg in 3.79 L
WATER (UNII: 059QF0KO0R)	0.902 kg in 3.79 L
ISOPROPYL ALCOHOL (UNII: ND2M416302)	0.119 kg in 3.79 L
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0000379 kg in 3.79 L
GLYCERIN (UNII: PDC6A3C0OX)	0.019 kg in 3.79 L
PANTHENOL (UNII: WW9CM0O67Z)	0.002 kg in 3.79 L
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.019 kg in 3.79 L

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71849-101-01	3.79 L in 1 JUG; Type 0: Not a Combination Product	10/30/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M003	10/30/2020	

**Labeler** - Bonafide Innovations LLC (016579579)

**Registrant** - Bonafide Innovations LLC (016579579)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Bonafide Innovations LLC		016579579	manufacture(71849-101)