

## **HAND SANITIZER- alcohol solution**

**LiDestri Beverages, 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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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 80% 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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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, purified water USP

### Package Label - Principal Display Panel

4.50"

3.75"

**hand sanitizer**

*recipe*  
**21**

DRUG FACTS	
<b>ACTIVE INGREDIENT (S)</b>	<b>PURPOSE</b>
Alcohol 80% w/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. Flammable. Keep away from heat or flame.	
<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>	
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<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 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

**ALCOHOL ANTISEPTIC 80% • TOPICAL SOLUTION**

**HAND SANITIZER • NON-STERILE SOLUTION**

**RECIPE21.COM TO ORDER • 1 GAL (3.78 L)**

Manufactured by LiDestri Spirits, A Family Company • Recipe 21® • Rochester, NY 14606 • (866) 377-6701  
MADE UNDER EMERGENCY MEASURES. NOT FOR CONSUMPTION. NOT FOR RESALE.

0 77644 90284 7

3.50"

1.75"

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# hand sanitizer



ALCOHOL ANTISEPTIC 80% • TOPICAL SOLUTION

HAND SANITIZER • NON-STERILE SOLUTION



## DRUG FACTS

**ACTIVE INGREDIENT (S) PURPOSE**  
Alcohol 80% 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.

**50 ML**

**WARNINGS**  
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**DO NOT USE**  
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## DIRECTIONS

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**OTHER INFORMATION**  
• Store between 15-30C (59-86F)  
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**Inactive ingredients**  
glycerin, hydrogen peroxide, purified water USP

2.75"

# hand sanitizer

*recipe*  
21

ALCOHOL ANTISEPTIC 80% • TOPICAL SOLUTION

HAND SANITIZER • NON-STERILE SOLUTION

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MADE UNDER EMERGENCY MEASURES. NOT FOR CONSUMPTION. NOT FOR RESALE.

1.75 L

5.00"

CORE DIAM. 3





2.75"

4.00"

*recipe*  
**21**

# hand sanitizer

ALCOHOL ANTISEPTIC 80% • TOPICAL SOLUTION

HAND SANITIZER • NON-STERILE SOLUTION

• **RECIPE21.COM TO ORDER** •

MADE UNDER EMERGENCY MEASURES.  
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12.68 FL OZ (375 ML)



Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:75539-001
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	80 mL in 100 mL
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75539-001-01	375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
2	NDC:75539-001-02	1750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
3	NDC:75539-001-03	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
4	NDC:75539-001-04	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/07/2020	

**Labeler** - LiDestri Beverages, LLC (151558413)

**Registrant** - LiDestri Beverages, LLC (151558413)

Establishment				
Name	Address	ID/FEI	Business Operations	
LiDestri Beverages, LLC		151558413	manufacture(75539-001) , label(75539-001) , pack(75539-001)	