

## **AND BOBS YOUR UNCLE HAND SANITIZER- isopropyl alcohol liquid**

**Ambrose Cubed 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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### **Hand Sanitizer**

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. Isopropyl Alcohol (75%, 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)**

Isopropyl 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

glycerin, hydrogen peroxide, purified water USP

### Package Label - Principal Display Panel

**& BOB'S YOUR UNCLE**

# HAND SANITIZER

**JUST LIKE THAT.....**  
**KILLS 99.99% of ILLNESS BREEDING GERMS**

**Isopropyl Alcohol Antiseptic 75%**  
**Topical Solution**

**Antiseptic Hand Rub**  
**Non-Sterile Solution**

**16oz [473 mL]**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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.	
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Other information	
• Store between 15-30C (59-86F)	
• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	
Ambrose Cubed LLC, 6780 Hudepeth Rd., Merrihue, NC, 28075-USA	
EMERGENCY CONTACT NUMBER: 1-800-222-1222	

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# HAND SANITIZER

**JUST LIKE THAT.....**  
**KILLS 99.99% of ILLNESS BREEDING GERMS**

**Isopropyl Alcohol Antiseptic 75%**  
**Topical Solution**

**Antiseptic Hand Rub**  
**Non-Sterile Solution**

**8oz [236 mL]**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
• in children less than 2 months of age	
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When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
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**KILLS 99.99% of ILLNESS BREEDING GERMS**

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub  
Non-Sterile Solution**

**4oz [118 mL]**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<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.	
Directions	
<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>	
Other information	
<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	
<small>Amprobe Cubed LLC, 6780 Hudepeth Rd., Marriaburg, NC, 28075-USA</small>	
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**KILLS 99.99% of ILLNESS BREEDING GERMS**

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub  
Non-Sterile Solution**

**33.8oz [1000 mL]**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<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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**KILLS 99.99% of ILLNESS BREEDING GERMS**

**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub  
Non-Sterile Solution**

**2oz [59 mL]**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<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.	
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Directions	
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**Isopropyl Alcohol Antiseptic 75%  
Topical Solution**

**Antiseptic Hand Rub  
Non-Sterile Solution**

**1-Gallon [3785 mL]**

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<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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Other information	
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Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	
<small>Amprobe Cubed LLC, 6780 Hudepeth Rd., Marriaburg, NC, 28075-USA</small>	
EMERGENCY CONTACT NUMBER: 1-800-222-1222	

3785mL NDC: 74758-007-08

AND BOBS YOUR UNCLE HAND SANITIZER

isopropyl alcohol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74758-007
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74758-007-04	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
2	NDC:74758-007-08	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
3	NDC:74758-007-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
4	NDC:74758-007-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
5	NDC:74758-007-03	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	
6	NDC:74758-007-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/09/2020	

**Labeler** - Ambrose Cubed LLC (117170612)

## Establishment

Name	Address	ID/FEI	Business Operations
Ambrose Cubed LLC		117170612	manufacture(74758-007)