

## **HAND SANITIZER- benzalkonium chloride spray**

**Sell-Able 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. 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)**

BENZALKONIUM CHLORIDE .12 g/100mL

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. Helps to prevent cross-contamination

### **Warnings**

For external use only.

### **When using this product**

- Do not use in or near eyes

Stop use and ask a doctor if irritation or redness develop.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

### **Other information**

- Store in a cool dry place below 104 degrees F (40C)

### **Inactive ingredients**

GLYCERIN (UNII: PDC6A3C0OX)  
PHENOXYETHANOL (UNII: HIE492ZZ3T)  
DEHYDROACETIC ACID (UNII: 2KAG279R6R)  
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)  
BENZYL ALCOHOL (UNII: LKG8494WBH)  
SODIUM HYDROXIDE (UNII: 55X04QC32I)  
WATER (UNII: 059QF0KO0R)  
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)  
POLOXAMER 124 (UNII: 1S66E28KXA)  
D&C GREEN NO. 8 (UNII: I2W85YOX9L)

#### Directions

- Receive a small amount of foam into palm of hand.
- Rub thoroughly over all surfaces of both hands
- Rub hands together until dry.

#### Package Label - Principal Display Panel

### ***Drug facts***

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#### ***Active ingredient[s]***

Benzalkonium Chloride 0.12% ..... Antiseptic

#### ***Purpose***

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#### ***Use[s]***

Sanitize hands to help reduce bacteria that potentially can cause disease.  
Helps to prevent cross-contamination

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#### ***Warnings***

**For external use only**

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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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**Stop use and ask a doctor if irritation or redness develop.**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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#### ***Directions***

• Shake to activate • Spray on the palms of your hands • Rub thoroughly over surface of both hands until dry

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#### ***Other information***

Store in a cool dry place below 104°F(40°C)

## ***Inactive ingredients***

Benzyl Alcohol, Cocamidopropyl Betaine, Dehydroacetic Acid, D&C Green No.8, Glycerin, Phenoxyethanol, Poloxamer 124, Sodium Hydroxide, Water

Distributed By: Sell-Able, LLC  
Anaheim, CA 92806  
NDC # 75094-007-08  
Made in USA  
1-949-535-4798



## **HAND SANITIZER**

benzalkonium chloride spray

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75094-007
<b>Route of Administration</b>	TOPICAL		

### **Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	12 g in 100 mL

### **Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>D&amp;C GREEN NO. 8</b> (UNII: I2W85YOX9L)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>POLOXAMER 124</b> (UNII: 1S66E28KXA)	

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75094-007-07	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75094-007-08	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	03/30/2020	

**Labeler** - Sell-Able LLC (080963581)

Revised: 5/2020

Sell-Able LLC