# HAND SANITIZER- alcohol gel Commercial Beverage Concepts, 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 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. Condition persists for more than 72 hours.

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

### **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.

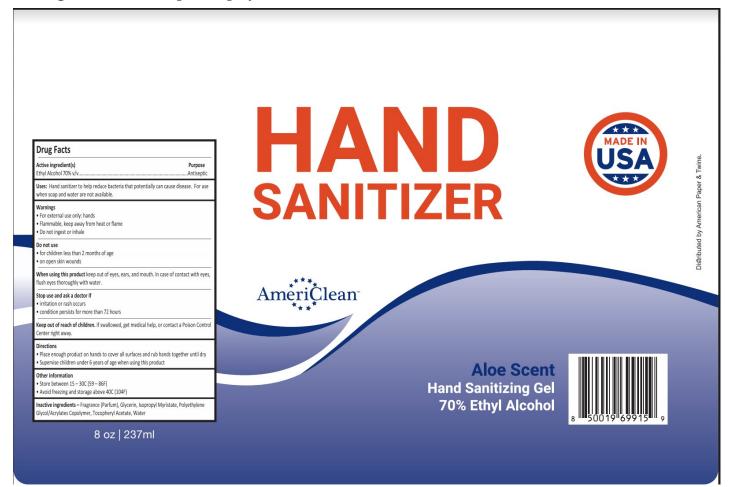
### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

# **Inactive ingredients**

Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water

# **Package Label - Principal Display Panel**



237mL, NDC: 75594-070-08

# HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:75594-070(NDC:74221-004)

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 L in 1 L		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
.ALPHATO CO PHERO L ACETATE, DL- (UNII: WR1WPI7EW8)	

Product Characteristics		
Color	Scor	e
Shape	Size	
Flavor	Impr	int Code
Contains		

l	Packaging						
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 NDC:75594-070-	0.237 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/23/2020				



# Labeler - Commercial Beverage Concepts, LLC (080925174)

Establishment				
Name	Address	ID/FEI	Business Operations	
Commercial Beverage Concepts, LLC		080925174	pack(75594-070), label(75594-070), repack(75594-070), relabel(75594-070)	

Revised: 7/2020 Commercial Beverage Concepts, LLC