

**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

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

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

## Package Label - Principal Display Panel

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v	Purpose Antiseptic
<b>Uses:</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: hands	
• Flammable, keep away from heat or flame	
• Do not ingest or inhale	
<b>Do not use</b>	
• for children less than 2 months of age	
• on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, flush eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b>	
• irritation or rash occurs	
• condition persists for more than 72 hours	
<b>Keep out of reach of children.</b> If swallowed, get medical help, or contact a Poison Control Center right away.	
<b>Directions</b>	
• Place enough product on hands to cover all surfaces and rub hands together until dry	
• Supervise children under 6 years of age when using this product	
<b>Other information</b>	
• Store between 15 – 30C (59 – 86F)	
• Avoid freezing and storage above 40C (104F)	
<b>Inactive ingredients</b> – Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	

8 oz | 237ml

**MADE IN USA**

**HAND SANITIZER**

AmeriClean™

**Aloe Scent**  
**Hand Sanitizing Gel**  
**70% Ethyl Alcohol**

8 50019 69915 9

Distributed by American Paper & Twine.

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)

Route of Administration TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 L in 1 L

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

**Product Characteristics**

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75594-070-08	0.237 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/23/2020	

# HAND SANITIZER



Distributed by American Paper & Twine.

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<b>Inactive ingredients</b> – Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	



**Aloe Scent**  
Hand Sanitizing Gel  
70% Ethyl Alcohol



8 oz | 237ml

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333E	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