

**COASTAL HAND SANITIZER GEL- hand sanitizer gel gel**  
**U.S. BEVERAGE, INC.**

*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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Coasstal Hand Sanitizer Gel hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade active ingredient in the preparation of the product (percentage in final product formulation)

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20

**Inactive Ingredients**

- a. Glycerol (7.6% v/v).
- b. Isopropyl Alcohol ((0.3% v/v)
- c. Hydrogen peroxide (0.1% v/v).
- d. Carbomer (0.4%)
- e. Vitamin E (0.3% v/v)
- f. Sterile distilled water

Label Gallon Bottle with FDA Logo 1 gallon

**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.

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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


glycerin, hydrogen peroxide, Isopropyl Alcohol, Carbomer, Vitamin E, and purified water USP





### Package Label - Principal Display Panel

3785 mL NDC: 79076-900-41

Label Gallon Bottle with FDA Logo 1 gallon

Label Gallon Bottle with FDA Logo 1

Drug Facts	
ACTIVE INGREDIENTS Ethyl Alcohol 70% v/v	PURPOSE Antiseptic
USES • Hand sanitizer to help decrease bacteria on the skin. When water, soap and towel are not available. • Recommended for repeated use.	
WARNINGS • For external use only. Flammable. Keep away from fire or flame. Do not apply around eyes. Do not use in ears & mouth. When using this product, avoid contact with eyes. In case of contact flush eyes with water. Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours. Keep out of reach of children. Children must be supervised in use of this product.	
DIRECTIONS • Pump as needed into your palms and thoroughly spread on both hands. Rub into skin until dry.	
OTHER INFORMATION • Store at 20° C (68° to 77° F). • May discolor fabrics.	
INACTIVE INGREDIENTS • Water, Isopropyl Alcohol, Glycerin, Carbomer and Hydrogen Peroxide, Vitamin E	
PACKAGED UNDER THE AUTHORITY OF COASTAL PACKAGING, INC. NEWNAN, GA.  030655600067	

  
**Coastal**  
Antimicrobial  
**ES HAND SANITIZER  
GEL**  
This product is a high quality Antimicrobial Hand Sanitizer that meets or exceeds the requirements of the USDA.  
  
Extra Soft  
Made with  
Glycerin & Vitamin E  
NDC NO.  
79076 900 41  
  
  
www.coastalpackaging.com  
Net Contents: 1 Gallon/128 fl oz

gallon Drug Facts

## COASTAL HAND SANITIZER GEL

hand sanitizer gel gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79076-900
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2649.5 mL in 3785 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	151.4 mL in 3785 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	113.55 mL in 3785 mL
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	11.355 mL in 3785 mL
GLYCERIN (UNII: PDC6A3C0OX)	287.66 mL in 3785 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	37.85 mL in 3785 mL
WATER (UNII: 059QF0KO0R)	533.685 mL in 3785 mL

Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79076-900-41	00 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
2	NDC:79076-900-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
3	NDC:79076-900-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
4	NDC:79076-900-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
5	NDC:79076-900-25	9463 mL in 1 BAG; Type 0: Not a Combination Product	07/01/2020	
6	NDC:79076-900-27	1040988 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/01/2020	



# Antimicrobial E3 HAND SANITIZER

This product is a high quality Antimicrobial Hand Sanitizer that meets or exceeds the requirements of the USDA.

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/26/2020	

**Labeler** - U.S. BEVERAGE, INC. (180035917)

## Establishment

Name	Address	ID/FEI	Business Operations
U.S. BEVERAGE, INC.		180035917	manufacture(79076-900)