

**TEN HAND SANITIZER- ethyl alcohol gel**  
**GASCO INDUSTRIAL CORP**

*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.*

-----

**TEN 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. 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)**

Ethyl 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. 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

- 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

Deionized water, Acrylates/C10-30 alkyl acrylate crosspolymer, Triethanolamine, EDTA.

### Package Label - Principal Display Panel

Drug Facts	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol (70%),...	Antimicrobial
<b>Uses</b>	
• Cleans skin & kills bacteria.	
<b>Warnings</b>	
• For external use only.	
• <b>FLAMABLE.</b> This product contains ethyl alcohol. Keep away from source of ignition.	
• If swallowed, get medical help or contact Poison Control Center right away.	
• <b>KEEP OUT OF REACH OF CHILDREN.</b>	
<b>Directions</b>	
• Place enough product in your palm to thoroughly spread on both hands and rub into the skin until dry.	
• Children under 6 years of age should be supervised when using this product.	
<b>Inactive Ingredients</b>	
Deionized Water, Acrylates/C10-30 alkyl acrylate crosspolymer, EDTA, Triethanolamine.	
<b>Questions of Comments?</b>	
Call: (787)737-4000	

**Net Contents: 16 oz. (473 mL)**

MADE IN USA  
Distributed by: MCI  
Luchetti Industrial Park  
Bayamón, P.R. 00960  
For information or comments  
Contact: 1-800-373-6983

0 74527 90535 3

473 mL NDC: 70185-100-20

## TEN HAND SANITIZER

ethyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70185-100
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.75 mL in 100 mL
EDETIC ACID (UNII: 9G34HU7RV0)	0.1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	33.3 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70185-100-20	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

**Labeler** - GASCO INDUSTRIAL CORP (616206756)

Revised: 4/2020

GASCO INDUSTRIAL CORP