GASCO 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.

GASCO 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.

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.

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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

GASCO Hand Sanitizer 800 mL

Gascō Hand Sanitizer Gel

Drug Facts

Active Ingredient

Purpose

Ethyl Alcohol (70%).....

Antimicrobial

Uses

Cleans Skin & kills bacteria.

Warnings

· For external use only.

FLAMABLE. This product contains ethyl alcohol.
 Keep away from source of ignition.

 If swallowed, get medical help or contact a Poison Control Center right away.

• KEEP OUT OF REACH OF CHILDREN.

Directions

 Place enough product in your palm to thoroughly spread on both hands and rub into the skin untill dry.

 Children under 6 years of age should be supervised when using this product.

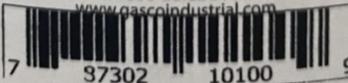
Inactive Ingredients

Deiorized Water, Acrylates/C10-30 alkyl acrylate crosspolymer, EDT, Triethanolamine.

Questions or Comments? Phone (787) 737-4000.

Net Contents: 800 mL (27 FL. OZ.)

Manufactured by: Gasco Industrial PO Box 1360 Gurabo PR 00778





Hand Sanitizer Gel

Drug Facts

Active Ingredient

Ethyl Alcohol (70%)

Purpose

...... Anámicrobial

Uses

Cleans Skin & kills bacteria.

Warnings

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Inactive Ingredients

Deiorized Water, Acrylates/C10-30 alkyl acrylate crosspolymer, EDT, Triethanolamine.

Questions or Comments? Phone (787) 737-4000.

Net Contents: 1000 mL (33.8 FL. OZ.)

Manufactured by: Gasco Industrial PO Box 1360 Gurabo PR 00778 www.gascoindustrial.com



GASCO HAND SANITIZER

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70185-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
TRO LAMINE (UNII: 903K93S3TK)	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: 059QF0KO0R)	33.3 mL in 100 mL	

	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:70185-500-70	1000 mL in 1 BAG; Type 0: Not a Combination Product	04/27/2020		
ı	2 NDC:70185-500-80	800 mL in 1 BAG; 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: 7/2020 GASCO INDUSTRIAL CORP