

HAND SANITIZER- alcohol gel
Jorge Martin Gomez Sanchez

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.

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) (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.
- b. Sterile distilled water or boiled cold water
- c. Isopropyl alcohol
- d. Carbomer 940
- e. Glycerin
- f. Triethanolamine
- g. Aloe Vera Leaf

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.

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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

Water, isopropyl alcohol, carbomer 940, glycerin, triethalonamine, aloe vera leaf

Package Label - Principal Display Panel

1 Gallon NDC: 78471-002-01



BE GERM-FREE
Ethyl Alcohol 70%
HAND SANITIZER
Antiseptic Gel

Kills Germs* | Softens Hands
With **Aloe Vera** and **Glycerin**

Drug Facts

Active Ingredients
Ethyl Alcohol70%

Use
For handwashing to decrease bacteria on the skin.
Recommended for repeated use.

Warnings
For external use only.
Flammable, keep away from fire or flame.
In case of accidental ingestion, seek medical attention
or contact a poison control center immediately.

Directions
Receive a small amount of liquid into palm of hand.
Rub hands together until dry.
Rub thoroughly over all surfaces of both hands.

Other Information
Store in a cool, dry place, below 104° F.

Inactive Ingredients
Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

*Effective at eliminating 99% of many common harmful germs.

DISTRIBUTED BY:
PATRIOT MEDICAL GROUP
CHICAGO, IL

70% Alcohol
1 Gallon
3.8L



NDC:

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78471-002
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
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78471-002-01	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - jorge Martin Gomez Sanchez (951577703)**Establishment**

Name	Address	ID/FEI	Business Operations
Jorge Martin Gomez Sanchez		951577703	manufacture(78471-002)

Revised: 6/2020

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