## HAND SANITIZER- alcohol gel KARSOF SYSTEMS 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. Isopropyl Alcohol (75%, 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)**

Isopropyl Alcohol 75% 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**

elettaria cardamomum, azadirachta indica, syzygium aromaticum, cinnamomum camphora, aloe vera, phyllanthus emblica, carbomer, glycerin, hydrogen peroxide, purified water USP, rosa gallica, crocus sativus, coconut oil, olive oil

## Package Label - Principal Display Panel

473.176ml NDC 77160-399-06



## **Alcohol Antiseptic 70%**

Topical Gel

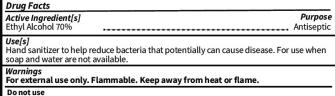
# **Hand Sanitizer**





3.38 fl. oz. (473.176 ml)





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## Inactive ingredients

Carbomer, Glycerin, Hydrogen Peroxide, Purified water USP







## HAND SANITIZER

alcohol gel

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HUMAN OTC DRUG NDC:77160-399 Product Type Item Code (Source)

Route of Administration TOPICAL

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ACTIVE	Ingre	are nt	ACTIVE	Moiety

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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)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:77160-399-	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/11/2020			

# Labeler - KARSOF SYSTEMS LLC (049125501)

# **Registrant -** Karsof systems LLC (049125501)

Establishment					
Name	Address	ID/FEI	Business Operations		
KARSOF SYSTEMS LLC		049125501	manufacture(77160-399)		

Revised: 9/2020 KARSOF SYSTEMS LLC