

**HAND SANITIZER- alcohol gel**  
**Medek, 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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**Kepter Hand Sanitizer**

This is a hand sanitizer manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

- 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. Glycerol (.5% v/v).
- c. Carbopol (0.5% v/v).
- d. Triethanolamine (0.4% v/v)
- e. Sterile distilled water or boiled cold water.

**Active Ingredient(s)**

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Antiseptic Hand Sanitizer to reduce germs on skin. For use when soap and water are not available.

**Warnings**

For external use only. Flammable. Keep away from open flame and sources of heat.

**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, rash or redness 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, rash or redness 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

Apply a small amount of product into hands and rub between both sides of hands until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

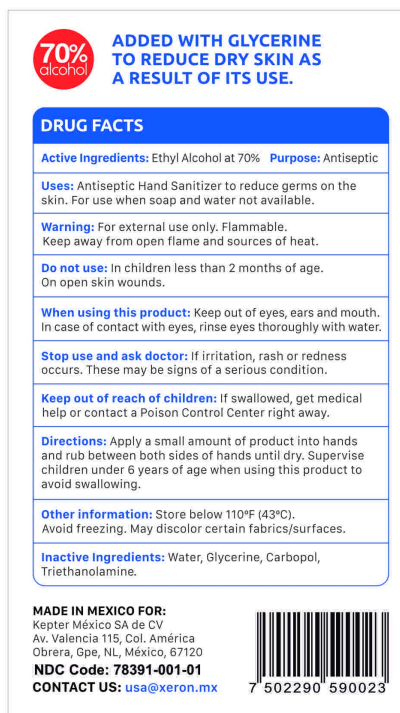
- Store below 110F (43C)
- Avoid freezing. May discolor certain fabrics/surfaces.

## Inactive ingredients

Water, glycerin, carbopol, Triethanolamine.

## Package Label - Principal Display Panel

976 mL NDC: 75432-003-01



3786 mL NDC: 75432-003-02



**70% alcohol** **ADDED WITH GLYCERINE TO REDUCE DRY SKIN AS A RESULT OF ITS USE.**

DRUG FACTS	
<b>Active Ingredients:</b> Ethyl Alcohol at 70%	<b>Purpose:</b> Antiseptic
<b>Uses:</b> Antiseptic Hand Sanitizer to reduce germs on the skin. For use when soap and water not available.	
<b>Warning:</b> For external use only. Flammable. Keep away from open flame and sources of heat.	
<b>Do not use:</b> In children less than 2 months of age. On open skin wounds.	
<b>When using this product:</b> Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask doctor:</b> If irritation, rash or redness occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children:</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions:</b> Apply a small amount of product into hands and rub between both sides of hands until dry. Supervise children under 6 years of age when using this product to avoid swallowing.	
<b>Other information:</b> Store below 110°F (43°C). Avoid freezing. May discolor certain fabrics/surfaces.	
<b>Inactive Ingredients:</b> Water, Glycerine, Carbopol, Triethanolamine.	

**MADE IN MEXICO FOR:**  
 Kepter México SA de CV  
 Av. Valencia 115, Col. América  
 Obrera, Gpe, NL, México, 67120  
**NDC Code: 78391-001-02**  
**CONTACT US: [usa@xeron.mx](mailto:usa@xeron.mx)**

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75432-003
<b>Route of Administration</b>	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
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	28 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.4 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75432-003-01	976 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75432-003-02	3786 mL in 1 BOTTLE; 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** - Medek, LLC (055524072)

## Establishment

Name	Address	ID/FEI	Business Operations
Medek, LLC		055524072	manufacture(75432-003)

Revised: 6/2020

Medek, LLC