

## **HAND SANITIZER- alcohol liquid**

**Petroleum & Water Chemicals Solutions, S. de R.L. de C.V.**

*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. Glycerol (5% v/v).
- c. Hydrogen peroxide (3% 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)**

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**

Glycerin, Hydrogen Peroxide, Purified Water USP

**Package Label - Principal Display Panel**

DAILY USE  
GEL

# Freshly

ANTIBACTERIAL

70%  
ALCOHOL

ELIMINATES  
99.9%  
of Germs and Bacteria

**ACTIVE INGREDIENTS:**

Alcohol - 70%

**INACTIVE INGREDIENTS:**

Purified Water  
Glycerin  
Hydrogen Peroxide



PETROLEUM & WATER  
CHEMICAL SOLUTIONS  
RFC: PAW130628BQA

Av. Campestre del Lago #174 Col. Campestre de  
Lago, Cuauhtlan Izcalli, México.



FRE052020

**DIRECTIONS**

Place product on hand rub  
until dry.

**USES**

To help reduce bacteria  
on the skin.

When using this product  
do not use in or near the eyes.  
In case of contact,  
rinse eyes thoroughly with water.

**WARNINGS**

Flammable, keep away from  
fire and flame.

For external use only

**OTHER INFORMATION**

- Store between 15-30c (59-86f)  
- Avoid freezing and excessive  
heat above 40c (104f)

**250ml.**

250 mL NDC: 77674-0250-7

**HAND SANITIZER**

alcohol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77674-0250	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	175 mL in 250 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
GLYCERIN (UNII: PDC6A3C0OX)			12.5 mL in 250 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			7.5 mL in 250 mL	
WATER (UNII: 059QF0K00R)			55 mL in 250 mL	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77674-0250-7	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	05/11/2020		

**Labeler** - Petroleum & Water Chemicals Solutions, S. de R.L. de C.V. (951577599)

**Registrant** - Petroleum & Water Chemicals Solutions, S. de R.L. de C.V. (951577599)

### Establishment

Name	Address	ID/FEI	Business Operations
Petroleum & Water Chemicals Solutions, S. de R.L. de C.V.		951577599	manufacture(77674-0250) , label(77674-0250)

Revised: 5/2020

Petroleum & Water Chemicals Solutions, S. de R.L. de C.V.