

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.

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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

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: PWW1306289QA

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)

500ml.

500 mL NDC: 77674-0500-7

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77674-0500	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	350 mL in 500 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)			25 mL in 500 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			15 mL in 500 mL	
WATER (UNII: 059QF0K00R)			110 mL in 500 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77674-0500-7	500 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 - 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(77674-0500) , label(77674-0500)

Revised: 5/2020

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