

**HAND SANITIZER- isopropyl alcohol liquid**  
**PHARMATEC PAKISTAN (PRIVATE) LIMITED**

*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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**Pharmatec 75% Isopropyl Alcohol Hand Sanitizer - 70 and 140 ml**  
**US FDA Temporary Policy**

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

**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**

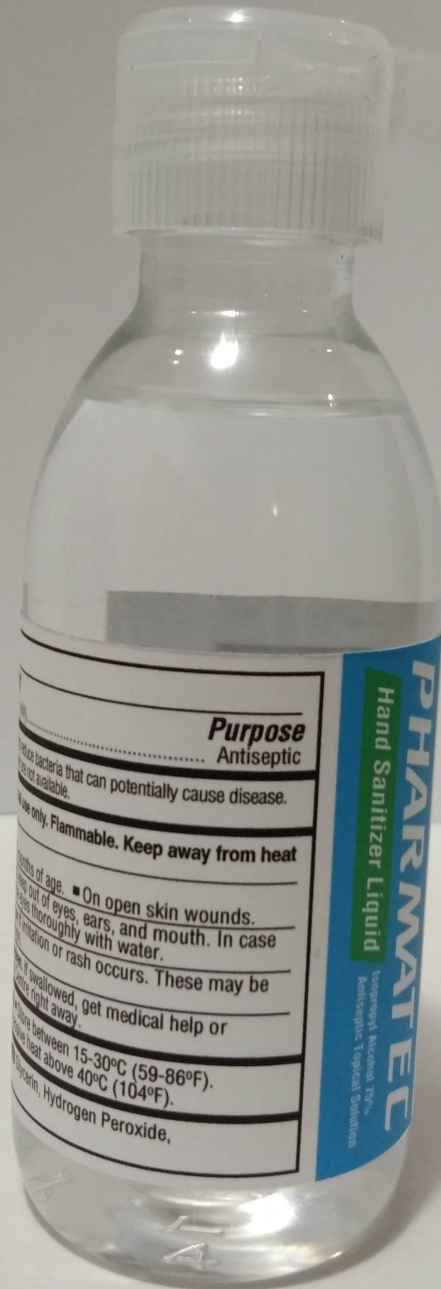
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- **Questions or comments ?**
- E-mail sanitizer.usa@pharmatec.com or
- Call Toll Free 1-833-PHARTEC (742 7832)

**Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel for 140 ml SKU**

[140ml NDC 79665-001-14]



**Purpose**  
Antiseptic

..... Antiseptic  
..... bacteria that can potentially cause disease.  
..... available.

..... only. Flammable. Keep away from heat

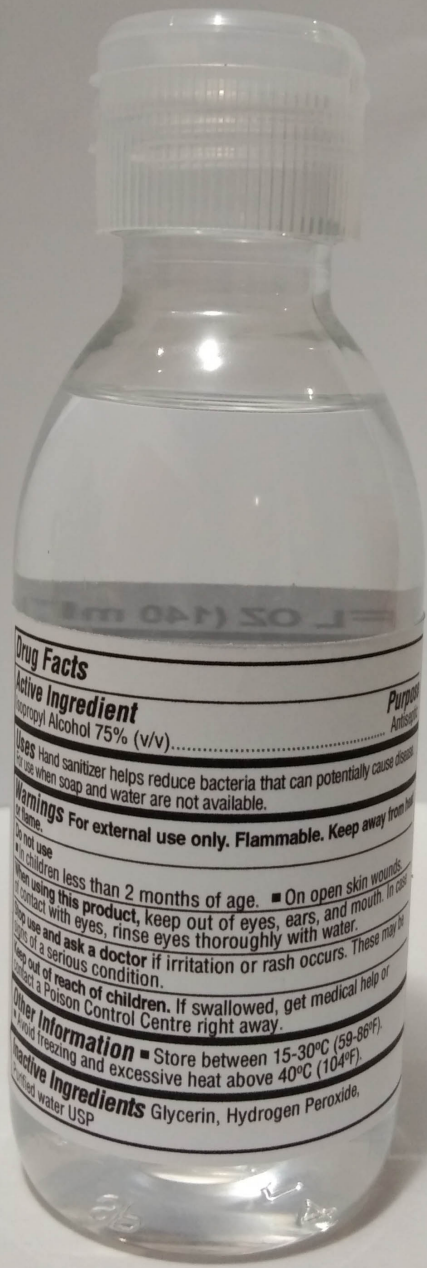
..... of age. ■ On open skin wounds.  
..... out of eyes, ears, and mouth. In case  
..... thoroughly with water.  
..... or rash occurs. These may be

..... swallowed, get medical help or  
..... right away.

..... between 15-30°C (59-86°F).  
..... heat above 40°C (104°F).

..... Hydrogen Peroxide,

**PHARMATEC**  
Hand Sanitizer Liquid  
Isopropyl Alcohol 70%  
Antiseptic Topical Solution



**Drug Facts**

**Active Ingredient**

Isopropyl Alcohol 75% (v/v)

**Purpose**  
Antisepic

**Uses** Hand sanitizer helps reduce bacteria that can potentially cause disease. Use when soap and water are not available.

**Warnings** For external use only. Flammable. Keep away from heat and flame.

Do not use in children less than 2 months of age. ■ On open skin wounds.

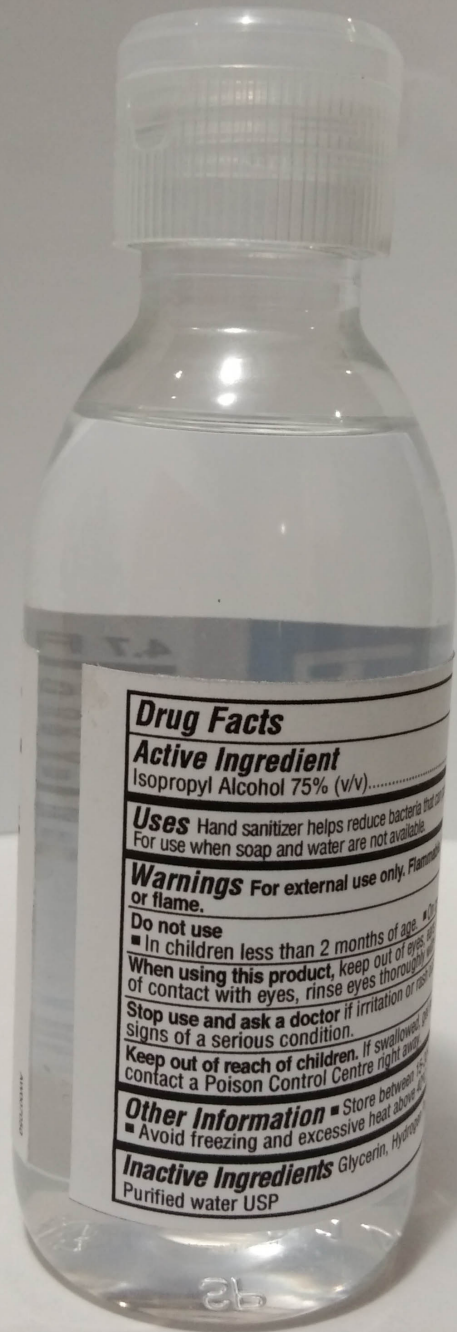
When using this product, keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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 Centre right away.

**Other Information** ■ Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients** Glycerin, Hydrogen Peroxide, Purified water USP



**Drug Facts**

**Active Ingredient**

Isopropyl Alcohol 75% (v/v).....

**Uses** Hand sanitizer helps reduce bacteria that can cause illness. For use when soap and water are not available.

**Warnings** For external use only. Flammable liquid and vapor. Avoid contact with flame.

**Do not use** In children less than 2 months of age.

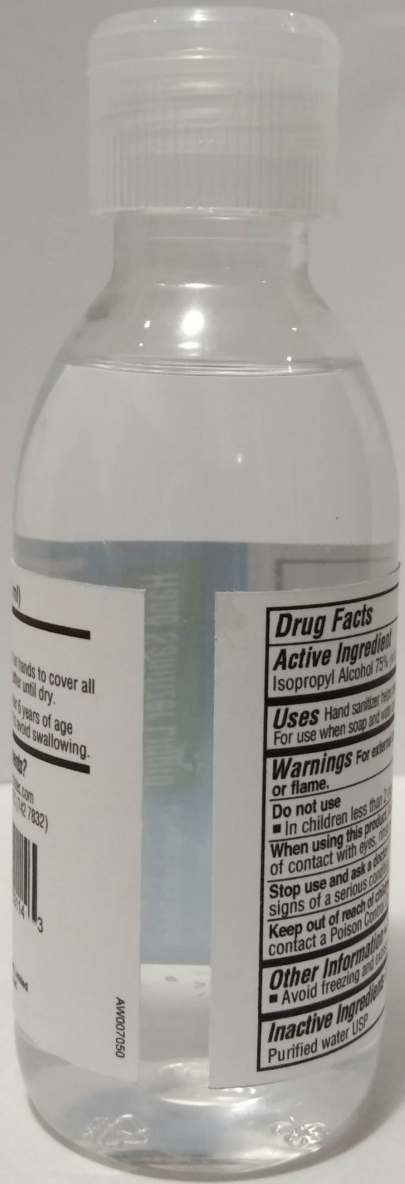
**When using this product**, keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask a doctor** if irritation or rash develops. Stop use if you experience signs of a serious condition.

**Keep out of reach of children.** If swallowed, contact a Poison Control Centre right away.

**Other Information** Store between 59°F and 86°F. Avoid freezing and excessive heat above 104°F.

**Inactive Ingredients** Glycerin, Hydroxyethylcellulose, Purified water USP



**Drug Facts**

**Active Ingredient**

Isopropyl Alcohol 75%

**Uses** Hand sanitizer

For use when soap and water are not available.

**Warnings** For external use only.

Do not use if you are pregnant or breastfeeding.

When using this product, avoid contact with eyes, nose, mouth, and throat.

Stop use and ask a doctor if you experience signs of a serious allergic reaction.

Keep out of reach of children. Contact your doctor if you experience symptoms of an allergic reaction.

**Other Information**

Avoid freezing and shaking.

**Inactive Ingredients**

Purified water USP

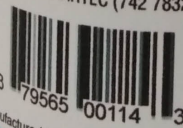
4.7 FL OZ (140 ml)

**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.

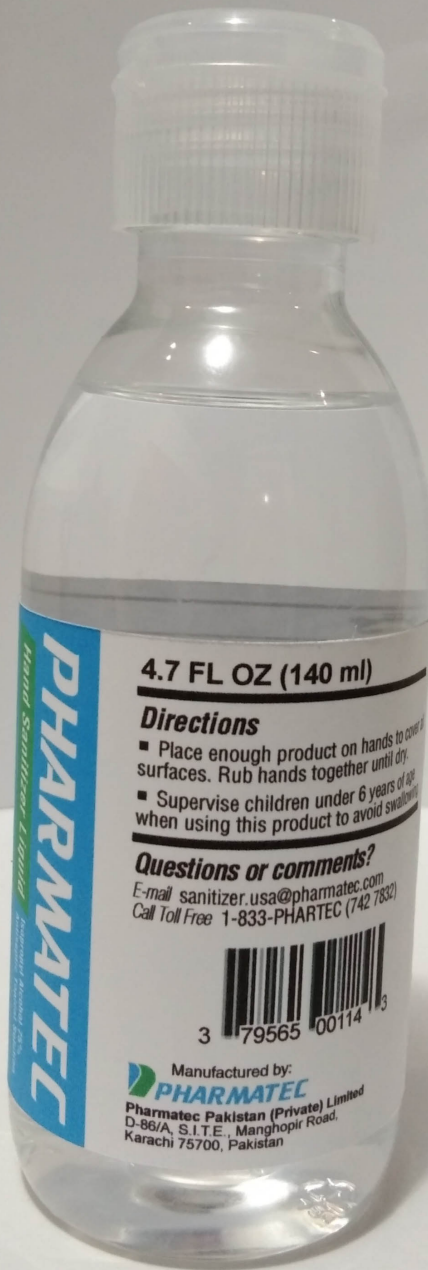
**Questions or comments?**

Email: sanitizer.usa@pharmatec.com  
Call Toll Free: 1-833-PHARTEC (742 7832)



Manufactured by:  
**PHARMATEC**  
Pharmatec Pakistan (Private) Limited  
P.O. Box 317, E. Manghopir Road,  
Karachi 75100, Pakistan

AMC07050



4.7 FL OZ (140 ml)

**Directions**

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- Supervise children under 6 years of age when using this product to avoid swallowing.

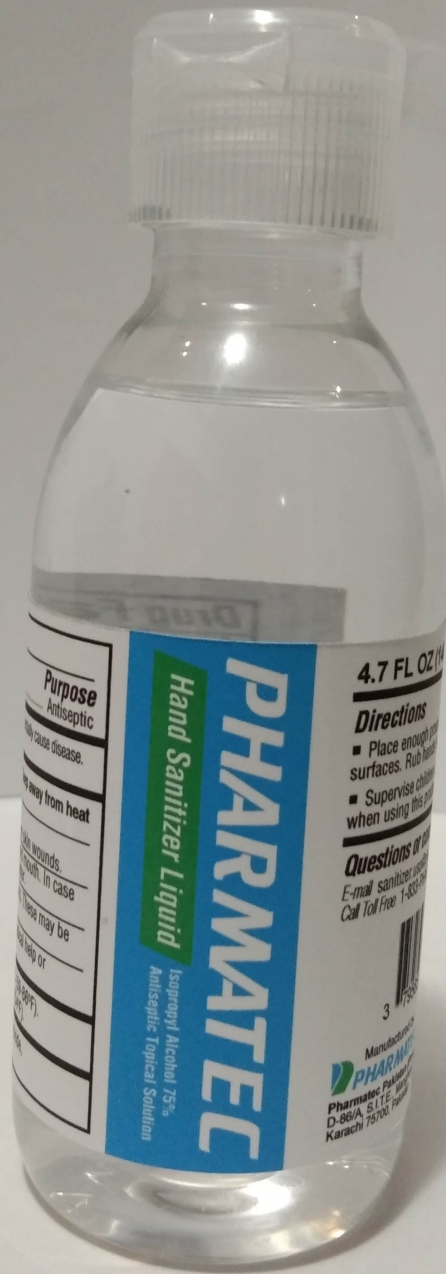
**Questions or comments?**

E-mail [sanitizer.usa@pharmatec.com](mailto:sanitizer.usa@pharmatec.com)  
Call Toll Free 1-833-PHARTEC (742 7832)



Manufactured by:  
**PHARMATEC**  
Pharmatec Pakistan (Private) Limited  
D-86/A, S.I.T.E., Manghopir Road,  
Karachi 75700, Pakistan





# HAND SANITIZER

isopropyl alcohol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79565-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79565-001-70	70 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/13/2020	
2	NDC:79565-001-14	140 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/13/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/13/2020	

**Labeler** - PHARMATEC PAKISTAN (PRIVATE) LIMITED (645373978)

**Registrant** - PHARMATEC PAKISTAN (PRIVATE) LIMITED (645373978)

## Establishment

Name	Address	ID/FEI	Business Operations
PHARMATEC PAKISTAN (PRIVATE) LIMITED		645373978	manufacture(79565-001)