

**HAND SANITIZER- alcohol gel**  
**Renopac, S.A 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.*

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**Active Ingredient(s)**

Alcohol 80% 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**

water, glycerin, carbomer, triethanolamine.

# Package Label - Principal Display Panel

## SANIKIT

HAND SANITIZER  
ANTIBACTERIA GEL

Contains 80% Ethyl alcohol

<b>Drug Facts</b>	
Active ingredient [s]	Purpose
Ethyl alcohol 80% v/v	Antiseptic
Use [s]	
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	
<ul style="list-style-type: none"> <li>• In children less than 2 months of age</li> <li>• on open skin sores</li> </ul>	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. There 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	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
Other information	
<ul style="list-style-type: none"> <li>• Store between 15-30°C (59-86°F)</li> <li>• Avoid freezing and excessive heat above 42°C (104°F)</li> </ul>	
Inactive ingredients: water, glycerin, carbomer, triethanolamine.	

MANUFACTURED FOR: Renopac, S.A de C.V  
PRODUCT OF MEXICO.

1000 mL NDC: 79067-001-01

1L

### HAND SANITIZER

alcohol gel

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79067-001
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

#### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
CARBOMER 1342 (UNII: 809Y72KV36)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
CUPRIC TRIETHANOLAMINE (UNII: 6NU949U74E)	0.125 mL in 100 mL

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79067-001-01	1000 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** - Renopac, S.A de C.V (823847215)

## Establishment

Name	Address	ID/FEI	Business Operations
Renopac, S.A de C.V		823847215	manufacture(79067-001) , pack(79067-001) , label(79067-001)

Revised: 6/2020

Renopac, S.A de C.V