

**HAND SANITIZER- alcohol gel**  
**SIMEX LOGISTICS, 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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**citrugel**

**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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**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, purified water ,d-LIMONENE,CARBORMER,TRILOMINE

**Package Label - Principal Display Panel**



ADVANCED GEL HAND SANITIZER


Liquid Gel With LIMONENE

70% Alcohol

Effectively Kills more than 99.99% of germs\*

\*Eliminates more than 99% of many common harmful germs and bacteria

33.81 FL OZ ( 1L )

<b>Drug Facts</b>	
<i>Active Ingredient[s]</i>	<i>Purpose</i>
Ethyl Alcohol 70.00%.....	Antimicrobial
<i>Use[s]</i>	
Helps reduce bacteria on the skin that could cause diseases.	
<i>Warnings</i>	
For external use only. Flammable. <b>Keep away from heat or flame.</b>	
<ul style="list-style-type: none"> <li>• When using this product do not use in or near the eyes.</li> <li>• In case of contact, rinse eyes thoroughly with water.</li> <li>• Stop use and ask a doctor if irritation or rash appears and lasts.</li> <li>• Keep out of reach of children.</li> <li>• If ingested, get medical help or contact a Poison Control Center right away.</li> </ul>	
<i>Directions</i>	
<ul style="list-style-type: none"> <li>• Place enough product in the palm of your hands to thoroughly cover your hands.</li> <li>• Rub hands together briskly until product is completely absorbed and hands are dry.</li> <li>• Not recommended for infants</li> <li>• Do not store above 105 degrees F</li> </ul>	
<i>Inactive Ingredients</i>	
Purified Water, D-Limonene, Carbomer, Triethanolamine, Glycerol.	
<i>Distributed By</i> CitruGel Inc. Henderson, NV 89052 www.citrugel.com	
 Made in Mexico	
<i>Produced By:</i> Simex Logistics S.A. de C.V Salvatierra No. 101 Fraccionamiento El Puente. Celaya, Guanajuato, Mexico.  DUNS number: 951578070	
 00860004105701	

1000 mL NDC: 74247-002-01

<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78247-002
<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	70 mL in 100 mL
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>

LIMONENE, (+)- (UNII: GFD7C86Q1W)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78247-002-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

**Labeler** - SIMEX LOGISTICS, S.A. de C.V. (951578070)

**Registrant** - SIMEX LOGISTICS, S.A. de C.V. (951578070)

### Establishment

Name	Address	ID/FEI	Business Operations
SIMEX LOGISTICS, S.A. de C.V.		951578070	manufacture(78247-002)

Revised: 9/2020

SIMEX LOGISTICS, S.A. de C.V.