

**HAND SANITIZER- alcohol gel**  
**SIMEX LOGISTICS SA DE CV**

*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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**HEALTH & HAND LABEL**

**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**

glycerol, carbomer, purified water , trolamine

**Package Label - Principal Display Panel**



1 L NDC: 78247-006-01

<b>HAND SANITIZER</b>		
alcohol gel		
<b>Product Information</b>		
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b> NDC:78247-006
<b>Route of Administration</b>	TOPICAL	
<b>Active Ingredient/Active Moiety</b>		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL
<b>Inactive Ingredients</b>		
Ingredient Name	Strength	

<b>CARBOMER HOMO POLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78247-006-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

**Labeler** - SIMEX LOGISTICS SA DE CV (951578070)

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