

**HAND SANITIZER- alcohol solution**  
**Chemical Solutions de México, 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.

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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, hydrogen peroxide, purified water USP

# Package Label - Principal Display Panel

Cleen Free

HAND SANITIZER  
80% ALCOHOL

1000 ml (1 L)

MANUFACTURED BY: CHEMICAL SOLUTIONS DE MEXICO, SA DE CV ALFAREROS NO. 647,  
 INTERIOR B, CALTEPEC DE MORELOS (SANTA CLARA), CDMX, PRODUCT OF  
 MEXICO.

Drug Facts	
Active ingredient [s]	Purpose
Ethyl alcohol 80% w/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	
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Active Ingredients:	
purified water USP, glycerin, hydrogen peroxide	

1000 mL NDC: 78672-001-01

## HAND SANITIZER

alcohol solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78672-001
Route of Administration	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
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:78672-001-01	1000 mL in 1 BOTTLE, DISPENSING; 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** - Chemical Solutions de México, S.A. de C.V. (813291820)

**Establishment**

Name	Address	ID/FEI	Business Operations
Chemical Solutions de México, S.A. de C.v.		813291820	manufacture(78672-001) , pack(78672-001) , label(78672-001)

Revised: 6/2020

Chemical Solutions de México, S.A. de C.V.