

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.

protect hands 1 gallon

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, water, carbomer, triethanolamine,

Package Label - Principal Display Panel

Drug Facts

Active ingredient[s] Purpose
Ethyl Alcohol 70%Antimicrobial

Use[s]
Helps reduce bacteria on the skin that could cause diseases.

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

- When using this product do not use in or near the eyes.
- In case of contact rinse eyes thoroughly with water.
- Stop use and ask a doctor if irritation or rash appears and lasts.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in the palm of your hands to thoroughly cover your hands.
- Rub hands together briskly until product is completely absorbed and hands are dry.
- Not recommended for infants
- Do not store above 105 degrees F.

Inactive ingredients:
Purified Water, Carbomer, Triethanolamine, Glycerol.

Distributed By:
PS Promotional Solutions LLC
Allen Street #406 Dallas, Texas 75204

Produced By:
Simex Logistics S. A. de C.V.
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 0 723707 893163

3780 mL NDC: 78247-008-10

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78247-008
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			

WATER (UNII: 059QF0KO0R)

TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78247-008-10	3780 mL in 1 JUG; Type 0: Not a Combination Product	07/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/07/2020	

Labeler - SIMEX LOGISTICS SA DE CV (951578070)

Revised: 9/2020

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