

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.

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,trolamine, water,carbormer,trilomine

Package Label - Principal Display Panel



70% ALCOHOL CONTENT
Kills 99.9% of all germs

33.8 FL OZ (1L)

Drug Facts	
Active Ingredient(s) Ethyl Alcohol 70.00%	Purpose 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 ingested, 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 Blue Ridge Southern Supply, LLC 1130 Aba St. Blue Ridge, GA 30513 www.brsupply.com	
 	
Produced By: Simex Logistics S.A. de C.V Salvatierra No. 101 Fraccionamiento El Puente. Celaya, Guanajuato, Mexico.	
 <p>Made in Mexico</p>	
DUNS number: 951578070	

1000 mL NDC: 78247-001-01

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78247-001
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)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78247-001-01	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	03/30/2020	

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(78247-001)

Revised: 9/2020

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