

HAND SANITIZER- alcohol gel
GIA EVOLUTION 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.

Active Ingredient(s)

Alcohol 72% 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

purified water USP, glycerin, carbomer, triethanolamine and vitamin E

Package Label - Principal Display Panel

2000mL NDC: 77231-060-11

127.397 mm

Drug Facts

Active Ingredient [s]	Purpose
Ethyl alcohol 72% v/v	Antiseptic

Use [s]
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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Other information

- Store between 15-30°C (59-86 °F)
- May discolor fabrics

Inactive Ingredients: Purified water USP, Glycerin, Carbomer, Triethanolamine.

MADE IN MEXICO BY:
 GIA EVOLUTION S.A. DE C.V.
 CARR. AGUASCALIENTES - ZACATECAS KM 8.
 COL. LA PERLA, AGUASCALIENTES,
 AGS. C.P. 20110. www.gjalv.com.
 PRODUCT OF MEXICO.

7 509546 045054

8000 mL NDC: 77231-060-12

10.4 cm

Drug Facts

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Ethyl alcohol 72% v/v	Antiseptic

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7 500107 959735
 HAND SANITIZER
 4 X 2 LITERS BOTTLE (8L) 72% ALCOHOL

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77231-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	1.5 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77231-060-12	8000 mL in 1 BOX; Type 0: Not a Combination Product	05/21/2020	
2	NDC:77231-060-11	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

Labeler - GIA EVOLUTION SA DE CV (951577293)

Registrant - GIA EVOLUTION SA DE CV (951577293)

Establishment

Name	Address	ID/FEI	Business Operations
GIA EVOLUTION SA DE CV		951577293	pack(77231-060) , manufacture(77231-060) , label(77231-060)