#### 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.

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#### **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)

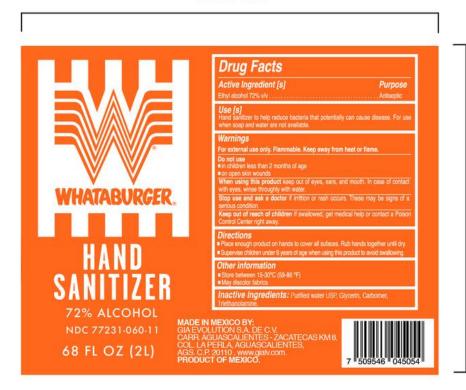
#### **Inactive ingredients**

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

### Package Label - Principal Display Panel

2000mL NDC: 77231-060-11

127.397 mm



100.409 mm

8000 mL NDC: 77231-060-12

10.4 cm



7.7 cm

## HAND SANITIZER

alcohol gel

Duadrest	Information
Product	Information

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

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

## **Inactive Ingredients**

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Ingredient Name	Strength	
CARBOMER 940 (UNII: 4Q93RCW27E)	1.5 g in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 903K93S3TK)	1 mL in 100 mL	

## Packaging

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

# **Marketing Information**

	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)

Revised: 6/2020 GIA EVOLUTION SA DE CV