

**HAND SANITIZER- alcohol gel**  
**FARMACIA SAN ARCANGEL, 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 Ingredients**

Ethyl alcohol 70% v/v

**Purpose**

Antiseptic

**Uses**

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 maybe signs of a serious condition.

**keep out of reach of children**

if swallowed, get medical help or contact a poison control center right away.

**Directions**

Put 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 (58-86F)

Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Water (aqua), Vegetable Glycerine UPC, Hydroxypropyl methylcellulose and carboxymethylcellulose.

**Principal Display**

Hand sanitizer

70% alcohol

68 fl. oz. (2.1qt) (2L)



<b>HAND SANITIZER</b>			
alcohol gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80535-0002
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)				
HYPROMELLOSE 2208 (60000 MPA.S) (UNII: 2F7T07H9ZD)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80535-0002-1	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/23/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/23/2020		

**Labeler** - FARMACIA SAN ARCANGEL, S.A DE C.V (951583068)

**Registrant** - FARMACIA SAN ARCANGEL, S.A DE C.V (951583068)

### Establishment

Name	Address	ID/FEI	Business Operations
FARMACIA SAN ARCANGEL S.A DE C.V		951583068	manufacture(80535-0002) , label(80535-0002) , pack(80535-0002)

Revised: 9/2020

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