**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 Ingredient**

Alcohol v/v 70%

**Purposes**

Antimicrobial

**Uses**

Hand sanitizer to decrease bacteria on the skin that could cause disease

Recommended for repetead use

**Warnings**

for external use only: hands

flammable, keep away from fire and flame

**When using this product**

keep out of eyes, do not use in or near eyes.

-in case of contact with eyes flush thorougly with water

-avoid contact with broken skin

-do not inhale or ingest

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**Stop use and ask a doctor if**

Irritation and redness develop

Condition persists for more than 72 hours

**keep out of reach of children**

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

**Directions**

put enough product in your palm to cover hands and rub hands together briskly until dry without wiping

for children uncer 6 years of age should be supervised when using

not recommended for infants

**Other information**

Store below 105 F (40 c)

may discolour certain fabrics

harmful to wood finishes and plastics

**Inactive Ingredients**

Purified water (aqua), Vegetable glycerin, Hydroxipropyl methylcellulose, carboxymethyl cellulose

**Principal Display**


Hand sanitizer gel

eliminates 99.9% of germs

70% alcohol

Natural ingredients hands soft

Contains moisturizers

640 fl oz/ 20 L

# HAND SANITIZER

alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:80535-0004 |
| **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** |
| **WATER** (UNII: 059QF0KO0R) | |
| **CARBOXYMETHYLCELLULOSE** (UNII: 05JZI7B19X) | |
| **HYPROMELLOSE 2208 (60000 MPA.S)** (UNII: 2F7T07H9ZD) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:80535-0004-1 | 20000 mL in 1 DRUM; Type 0: Not a Combination Product | 10/29/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 10/29/2020 | |

## 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 | label(80535-0004) , manufacture(80535-0004) , pack(80535-0004) |

Revised: 10/2020 FARMACIA SAN ARCANGEL, S.A DE C.V