

## **ALOE VERA HAND SANITIZER- isopropyl alcohol gel**

### **International Merchandise Group**

*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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Isopropyl Alcohol 75% 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, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

INSTANT HAND SANITIZER FOR EXTERNAL USE ONLY



## Drug Facts

### Active Ingredients

Ethyl alcohol 70%

### Purpose

Antiseptic

### DIRECTIONS

To decrease bacterias on the skin that could cause disease. Recommended for repeated use.

Wet hand thoroughly with product and allow to dry without wiping. For childrens under 6, use only under adult supervision. Not recommended for infants.

### WARNINGS

*Do not store above 105°F. May discolor some fabrics.  
Harmful to wood finishes and plastics.*

For hands external use only

• *Flammable, keep away from fire or flame* •

When using this products: Keep out of eyes. In case of contact with eyes, flush thoroughly with water.  
Avoid contact with broken skin. Do not inhale or ingest. Stop use and ask a doctor if irritation and redness appears or if 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.

### Inactive Ingredients

Aqua/Water, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Carbomer, Sodium Hydroxide, Aloe Vera.

INSTANT HAND SANITIZER FOR EXTERNAL USE ONLY

AL0420-001



MADE IN EL SALVADOR

INTERNATIONAL  
MERCHANDISE  
GROUP  
MIRAMAR FL.33027





70% Alcohol

hand  
sanitizer

aloe  
vera  
gel

*DESINFECTANTE de Manos*  
*NO GRASO - SIN ENJUAGUE*

NET CONTENTS 8.5 Fl. Oz. / 251 ml

INSTANT HAND SANITIZER FOR EXTERNAL USE ONLY

000 ml NDC: 00000-000-

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## ALOE VERA HAND SANITIZER

isopropyl alcohol gel

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:73971-246

|  |   |   |                             |                           |
|--|---|---|-----------------------------|---------------------------|
| <b>Route of Administration</b>   |   | TOPICAL   |                             |                           |
| <b>Active Ingredient/Active Moiety</b>                                     |   |   |                             |                           |
| <b>Ingredient Name</b>   |   | <b>Basis of Strength</b>  | <b>Strength</b>             |                           |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) |   | ISOPROPYL ALCOHOL   | 70 mL in 70 mL              |                           |
| <b>Inactive Ingredients</b>  |   |   |                             |                           |
| <b>Ingredient Name</b>   |   |   | <b>Strength</b>             |                           |
| GLYCERIN (UNII: PDC6A3C0OX)  |   |   | 70 mL in 70 mL              |                           |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V)                                       |   |   | 70 mL in 70 mL              |                           |
| WATER (UNII: 059QF0K00R)   |   |   | 70 mL in 70 mL              |                           |
| <b>Packaging</b>   |   |   |                             |                           |
| <b>#</b>   | <b>Item Code</b>                                | <b>Package Description</b>  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1  | NDC:73971-246-58                                | 251 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 03/30/2020                  |                           |
| <b>Marketing Information</b>   |   |   |                             |                           |
| <b>Marketing Category</b>  | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b>                                       | <b>Marketing End Date</b>   |                           |
| OTC monograph not final  | part333A  | 03/30/2020  |                             |                           |

**Labeler** - International Merchandise Group (555630446)

### Establishment

| Name                            | Address | ID/FEI    | Business Operations    |
|---------------------------------|---------|-----------|------------------------|
| International Merchandise Group |         | 555630446 | manufacture(73971-246) |

Revised: 4/2020

International Merchandise Group