

## **GEL ANTIBACTERIAL ALCOHOL- gel antibacterial alcohol gel**

**Sanchez, 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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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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 70% 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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away.

### 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

| DRUG FACTS  |  |
|---|--|
| <b>ACTIVE INGREDIENT</b>  | <b>PURPOSE</b>   |
| Ethyl Alcohol 70%   | Antiseptic   |
| <b>USES</b> • A hand sanitizer to help with a practical way to take care of your personal hygiene, added with natural essences to take care of your skin. |  |
| <b>WARNINGS</b> For external use only   |  |
| FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME OR SPARKS   |  |
| DO NOT USE NEAR EYES OR MOUTH. IN CASE OF CONTACT, RINSE EYES OR MOUTH THOROUGHLY WITH WATER.   |  |
| IN CASE OF IRRITATION OR RASH, STOP USE AND CONSULT YOUR DOCTOR.  |  |
| KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP.  |  |
| STORE IN DRY PLACES.  |  |
| <b>DIRECTIONS</b>   |  |
| • Apply to hands and distribute evenly until dry. Do not rinse.   |  |
| <b>OTHER INFORMATION</b>  | It is important to complement the use of Antibacterial Gel Botica el Olivo with proper hand washing. Cruelty free product. |
| <b>INACTIVE INGREDIENT</b>  | Water, triethanolamine, essential oils, aloe vera, glycerin, thickner, fragrance.  |
| <b>QUESTIONS OR COMMENTS?</b>   |  |
| Call +52 773.733.9730   |  |

ZAA003

MADE IN MEXICO

PRESENTACION: 200 L

INGLES

NDC:78316-001-01



# GEL ANTIBACTERIAL ALCOHOL

gel antibacterial alcohol gel

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:78316-001 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 70 mL in 70 mL |

## Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX)                           |          |
| TROLAMINE (UNII: 9O3K93S3TK)                          |          |
| WATER (UNII: 059QF0K00R)                              |          |
| SPIKE LAVENDER OIL (UNII: 7S2HYV1VJQ)                 |          |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) |          |

## Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78316-001-01 | 200000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020           |                    |
| 2 | NDC:78316-001-02 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product   | 03/30/2020           |                    |
| 3 | NDC:78316-001-03 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product    | 03/30/2020           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 03/30/2020           |                    |

**Labeler** - Sanchez, S.a. De C.v. (810011809)

**Registrant** - Sanchez, S.a. De C.v. (810011809)

## Establishment

| Name                  | Address | ID/FEI    | Business Operations    |
|-----------------------|---------|-----------|------------------------|
| Sanchez, S.a. De C.v. |         | 810011809 | manufacture(78316-001) |

