

## **HAND SANITIZER- antibacterial spray spray**

**Sanchez, S.a. De C.v.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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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)**

Citric Acid Monohydrate 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

**BOTICA EL OLIVO®**

# Antibacterial Spray

**KILLS 99.9% VIRUS, BACTERIAS AND GERMS** • **100% NATURAL** • **ALCOHOL FREE**

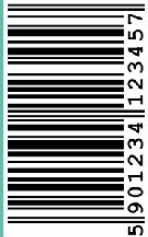
**EXTRA-BLEND WITH YOUR SKIN** • **DUSTS NOT AFFECT AIRWAYS** • **100% ORGANIC** • **WITH ALOE VERA** • **CRUELTY FREE**

**GS** Made in Mexico by Grupo Sánchez Oriente 171 No. 367, Col. Ampliación San Juan de Aragón, Gustavo A. Madero, Mexico City, Distrito Federal. (+52) 55-55118-1000. www.boticaelolivo.com

100ML

Expiration Date:      Lote:

ZAA001

DRUG FACTS	
<b>ACTIVE INGREDIENT</b>	<b>PURPOSE</b>
Citric Extracts	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	
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 OR REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP.	
STORE IN DRY PLACES.	
<b>DIRECTIONS</b>	 5 901234 123457
• 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, citric fragrance.
<b>QUESTIONS OR COMMENTS?</b>	
Call +52 773.733.9730	

**MADE IN MEXICO**

PRESENTACION: 100ML

INGLES

NDC:78316-003-02



**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78316-003-01	200000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78316-003-02	100 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
unapproved drug other		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(78316-003)

Revised: 6/2020

Sanchez, S.a. De C.v.