**HAND SANITIZER- isopropyl alcohol gel**
**LABORATPRIOS JM RODRIGUEZ**

*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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right 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

236.588 ml NDC: 77489-088-00 (8 OUNCES LABELFOR BOTTLE ) ( WHITE LABEL WITH GREEN IN THE FRONT AND BLUE LETTERS "MANITAS GEL" Z PLUS IOS THE BRAND FROM LABORATORIOS JM RODRIGUEZ ALSO MANITAS GEL IS A NICKNAME FOR HAND SANITIZER IN DOMINICAN REPUBLIC )


# HAND SANITIZER

isopropyl alcohol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:77489-088 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 75 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **GLYCERIN** (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| **HYDROGEN PEROXIDE** (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:77489-088-00 | 236.588 mL in 1 BOTTLE; 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 - LABORATPRIOS JM RODRIGUEZ (815941431)

## Registrant - LABORATORIOS JM RODRIGUEZ (815941431)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LABORATORIOS JM RODRIGUEZ | | 815941431 | manufacture(77489-088) |

Revised: 5/2020 LABORATPRIOS JM RODRIGUEZ