

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

**Laboratorios 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:

- 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.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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

473.176 ml NDC: 77489-016-00 (16 OUNCES LABEL FOR 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 )

**Modo de uso:** Aplique el producto en la palma de una mano. Frote las manos entre sí. Restriegue el producto sobre todas las superficies de las manos y los dedos hasta que se sequen.

**Advertencias:** Manténgase lejos del alcance de los niños, a una temperatura por debajo de los 40° C. En caso de contacto con los ojos, lavar con abundante agua. Solo para uso externo.

**Use:** Apply product to the palm of a hand. Rub your hands together. Rub the product over all surfaces of hands and fingers until dry.

**Warnings:** Keep out of the reach of children, at a temperature below 40° C. In case of eye contact, flush with plenty of water. For external use only.



**Fabricado por /Made in:** Lab. J.M. Rodríguez  
Reg. Ind. No. 19504

**Distribuido por:** Expo Caribe Inc.

Tel.: 787-288-3535 /

Email: ventas@expocaribbean.com



Drug Facts	
Active Ingredient	Purpose
Isopropyl Alcohol 70% w/w	Antiseptic
<b>Uses:</b> For handwashing to decrease bacteria on the skin.	
<b>WARNINGS For external use only</b>	
<b>When using this product</b> avoid contact with eyes. If contact with eyes occurs, flush with water.	
<b>Stop use and ask a doctor</b> if irritation and redness develops and persists.	
<b>Keep out of reach of children.</b> If swallowed, seek prompt medical attention.	
<b>Flammable</b> Keep away from open flame. Do not store above 110°F.	
<b>Directions:</b> Wet hand thoroughly with product and allow to dry without wiping.	
<b>Other Information:</b> Non-staining, may discolor certain fabrics.	
<b>Inactive ingredients:</b> Purified Water, Triethanolamine, Carbomer, Citric Acid, Glycerin, DMDM Hydantoin, Fragrance.	
<b>Questions:</b> 809-472-9402	



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## HAND SANITIZER

isopropyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77489-016
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: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77489-016-00	473.176 mL in 1 BOTTLE, DISPENSING; 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** - Laboratorios JM Rodriguez (815941431)

**Registrant** - laboratorios JM Rodriguez (815941431)

Establishment			
Name	Address	ID/FEI	Business Operations
Laboratorios JM Rodriguez		815941431	manufacture(77489-016)