

## **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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### **Hand Sanitizer**

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 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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### Directions

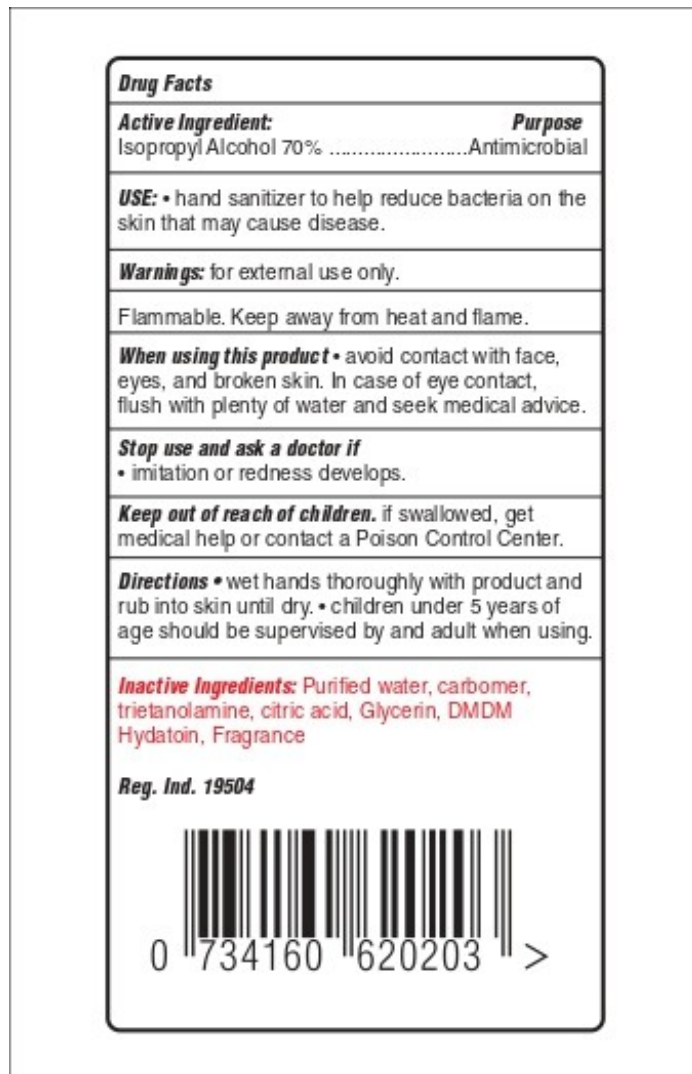
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

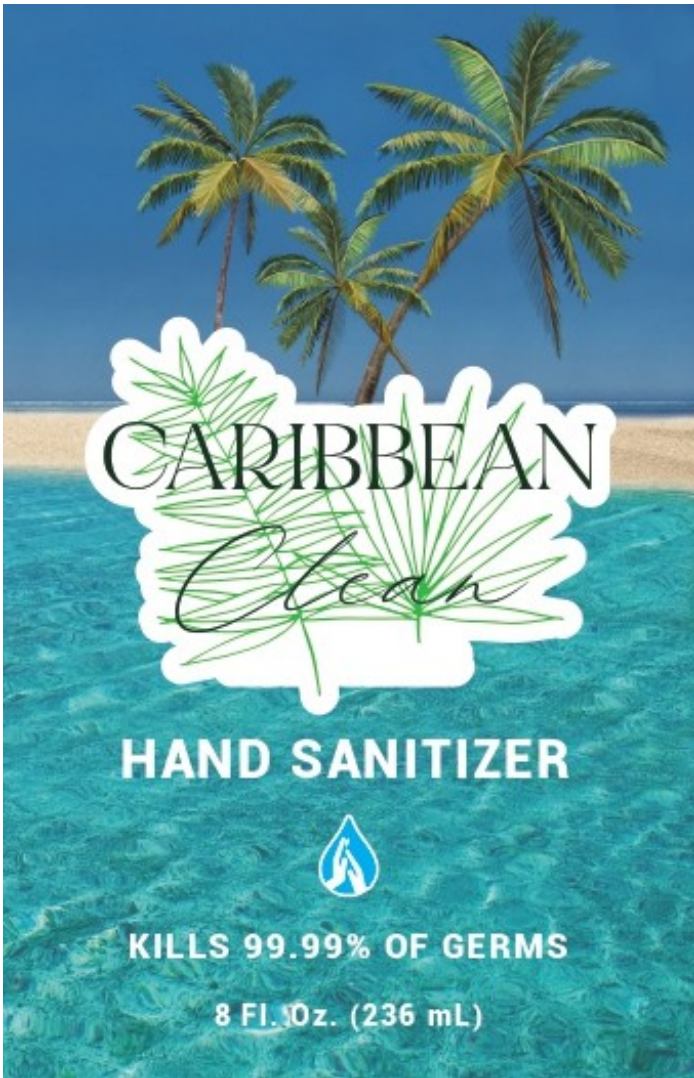
### Inactive ingredients

glycerin, Carbomer, trietanolamine, dmdm hidantoin, citric acid, purified water USP



### Package Label - Principal Display Panel

236 ml NDC: 77489-080-00



HAND SANITIZER			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77489-080
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	70 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)			0.15 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)			0.77 mL in 100 mL
CITRIC ACID ACETATE (UNII: DSO12WL7AU)			0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)			1 mL in 100 mL

WATER (UNII: 059QF0KO0R)				
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36 YHT392ID)				1 mL in 100 mL
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77489-080-00	236.58 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/16/2020	
2	NDC:77489-080-02	59.14 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/16/2020	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	10/16/2020	

**Labeler** - Laboratorios JM Rodriguez (815941431)

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Laboratorios JM Rodriguez		815941431	manufacture(77489-080)