

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

### **Laboratorios Lemuel SRL**

*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 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, carbomer, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**

236.56 ml NDC: 78475-271-12

<b>Directions</b>
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>
<b>Other information</b>
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>
<b>Inactive ingredients</b>
Purified Water, Glycerin, Hydrogen Peroxide and Carbomer homopolymer type A.
<b>Uso:</b> • Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen.
• Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.
<b>Otra Información:</b> • Almacenar entre 15-30C (59-86F)
• Evite la congelación y el calor excesivo por encima de 40C (104F)
<b>Ingredientes inactivos:</b> Agua Purificada, Glicerina, Hidrogeno Peróxido y Carbomer homopolymer type A.



<b>Drug Facts</b>
Active ingredient [s] Purpose Alcohol Isopropilico 75% v/v.....Antiseptic
<b>Use[s]</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Uso[s]</b> Desinfectante de manos para ayudar a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.
<b>Advertencias</b> Sólo para uso externo. Inflamable. Mantener alejado del calor o las llamas.
<b>No utilice</b> • en niños menores de 2 meses de edad • en heridas abiertas de la piel
<b>Cuando use este producto,</b> manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.
<b>Suspenda su uso y consulte a un médico</b> si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave.
<b>Mantener fuera del alcance de los niños.</b> En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.

Made in Dominican Republic by:  
**LEMUEL SRL**  
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 www.laboratorioslemuel.com



## HAND SANITIZER

isopropyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 78475-271
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII: ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE A</b> (UNII: F68VH75CJC)	3.6 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78475-271-10	59.14 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	
2	NDC:78475-271-11	118.28 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	
3	NDC:78475-271-12	236.56 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	
4	NDC:78475-271-13	473.12 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	
5	NDC:78475-271-14	3786 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	
6	NDC:78475-271-15	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	
7	NDC:78475-271-16	946.24 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/17/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/17/2020	

**Labeler** - Laboratorios Lemuel SRL (871488586)

**Registrant** - Laboratorios Lemuel SRL (871488586)

## Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Lemuel SRL		871488586	manufacture(78475-271)

Revised: 10/2021

Laboratorios Lemuel SRL