# 4 YOUR SAFETY HAND SANITIZER- alcohol gel Montenegro Castro, Carlos

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.

-----

# 4 your safety Hand sanitizer

## **Drug Facts**

## Active ingredient[s]

Ethyl Alcohol 70% v/v

# **Purpose**

Antimicrobial

### Use[s]

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 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.

## **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 15-30 ° C (59-86 ° F)
- Avoid freezing and excessive heat above 40 ° C (104 ° F)

### **Inactive ingredients**

# Package Labeling:60ml





### **Drug Facts**

Active ingredient[s] Ethyl Alcohol 70% v/v

Purpose Antimicrobia

**Use[s]**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

### 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.

### 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 15-30 °C (59-86 °F)

Made by:

Avoid freezing and excessive heat above 40°C (104°F)
 Inactive Ingredients Glycerin, Carbomer, Purified Water



LOT:

Package Labeling:250ml

# Label 250 ml





8.45 FL OZ (250 ml)

**KILLS HARMFUL BACTERIA AND GERMS** 

GrupoM

### **Drug Facts**

Active ingredient[s] Ethyl Alcohol 70% v/v

Purpose .Antimicrobial

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available

For external use only. Flammable. Keep away from heat or flame

**Do not use**• in children less than 2 months of age

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.

- 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.

- product to avoid swandwing.

  Other Information

  Store between 15-30 °C (59-86 °F)

  Avoid freezing and excessive heat above 40 °C (104 °F)

  Inactive Ingredients Glycerin, Carbomer, Purified Water

Made by:
Carlos Montenegro Castro
Veracruz, Mexico.
Distributed by:
For Inquiries:
grupomlimpieza@gmail.com
www.grupomlimpieza.com



MADE IN MÉXICO

LOT: FXP:

Package Labeling:500ml

# Label 500 ml





16.9 FL OZ(500 ml)

**KILLS HARMFUL BACTERIA AND GERMS** 

GrupoM

### **Drug Facts**

Active ingredient[s] Ethyl Alcohol 70% v/v

Purpose Antimicrobial

**Use[s]**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.

### 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 15-30°C (59-86°F)
- $\bullet$  Avoid freezing and excessive heat above 40 °C (104 °F) Inactive Ingredients Glycerin, Carbomer, Purified Water

Made by: Carlos Montenegro Castro Veracruz, México. Distributed by: For Inquiries: grupomlimpieza@gmail.com www.grupomlimpieza.com



MADE IN MÉXICO

LOT: EXP:

Package Labeling:1000ml

# **Label 1 Litro**





# **KILLS HARMFUL BACTERIA AND GERMS**

GrupoM

### **Drug Facts**

Active ingredient[s] Ethyl Alcohol 70% v/v

Purpose

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.

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

Inactive ingredients Glycerin, Carbomer, Purified Water

Made by: Carlos Montenegro Castro Veracruz, México. Distributed by: For Inquiries: grupomlimpieza@gmail.com www.grupomlimpieza.com





MADE IN MÉXICO

## **4 YOUR SAFETY HAND SANITIZER**

alcohol gel

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79252-001

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

ı	rictive ingredient retive wronety			
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL	

### **Inactive Ingredients**

Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
CARBO MER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
WATER (UNII: 059QF0KO0R)		

I	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:79252-001-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020			
2	NDC:79252-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020			
3	NDC:79252-001-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020			
4	NDC:79252-001-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/30/2020	

# Labeler - Montenegro Castro, Carlos (951577488)

Revised: 8/2020 Montenegro Castro, Carlos