

## **EMELY HAND SANITIZER- alcohol solution**

### **Laboratorios E&M 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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### **Emely 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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)**

Alcohol 80% 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.

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

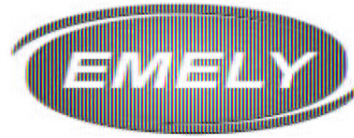
### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

### **Package Label - Principal Display Panel**

60 mL NDC: 77998-000-01

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 80% v/v.....	<b>Purpose</b> 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>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

Non-sterile Solution

KILLS 99.99% GERMS AND BACTERIAS



INSTANT HANDS CLEAN

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

Net Weight  
2 oz (60 ml)  
NDC: 77998-000-01



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<b>Otra in</b> • Almat • Evite por enc
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## Package Label - Principal Display Panel

120 mL NDC: 77998-000-02

<b>Drug Facts</b>	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 80% 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>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<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>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> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

Non-sterile Solution

KILLS 99.99% GERMS AND BACTERIAS



INSTANT HANDS CLEAN

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION



Net Weight  
4 oz (120 ml)  
NDC: 77998-000-02



**Informa**  
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**Ingredi**  
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**Package Label - Principal Display Panel**

240 mL NDC: 77998-000-03

<b>Drug Facts</b>	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 80% 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>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</b>	
<b>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</b>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	
<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> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

**Non-sterile Solution**

**KILLS 99.99% GERMS AND BACTERIAS**



**INSTANT HANDS CLEAN**

**ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION**

<b>Información del Producto</b>
Ingrediente (s) activo Propósito Alcohol 80% v / v ..... Antiséptico.
<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>
<b>Sólo para uso externo. Inflamable. Mantener alejado del calor o llamas.</b>
<b>No utilice</b>
<ul style="list-style-type: none"> <li>• en niños menores de 2 meses de edad</li> <li>• en heridas abiertas de la piel</li> </ul>
<b>Cuando use este producto, manténgalo fuera de los ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.</b>
<b>Suspenda su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave.</b>
<b>Mantener fuera del alcance de los niños. Si se ingiere, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.</b>
<b>Direcciones</b>
<ul style="list-style-type: none"> <li>• Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen.</li> <li>• Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.</li> </ul>
<b>Otra información</b>
<ul style="list-style-type: none"> <li>• Almacenar entre 15-30C (59-86F)</li> <li>• Evite la congelación y el calor excesivo por encima de 40C (104F)</li> </ul>
<b>Ingredientes inactivos</b> glicerina, peróxido de hidrógeno, agua purificada USP



Net Weight  
**8 oz (240 ml)**  
NDC: 77998-000-03



Para comentarios y sugerencias  
Tel.: 809-302-4542  
email: emiliofigu@halmat.com  
Elaborado por: Laboratorios E&M  
Santo Domingo, Rep. Dom.  
Reg. Ind. 22094

## Package Label - Principal Display Panel

480 mL NDC: 77998-000-04

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 80% v/v.....	<b>Purpose</b> 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>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

**Non-sterile Solution**

**KILLS 99.99% GERMS AND BACTERIAS**



**INSTANT HANDS CLEAN**

**ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION**

<b>Información del Producto</b> Ingrediente (s) activo Propósito Alcohol 80% v / v ..... Antiséptico.
<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 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> Si se ingiere, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.
<b>Direcciones</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> glicerina, peróxido de hidrógeno, agua purificada USP



Net Weight  
**16 oz (480 ml)**

NDC: 77998-000-04



Para comentarios y sugerencias  
Tel.: 809-302-4542  
email: emiliofogu@hotmail.com  
Elaborado por: Laboratorios E&M  
Santo Domingo, Rep. Dom.  
Reg. Ind. 22054

## Package Label - Principal Display Panel

960 mL NDC: 77998-000-05

<b>Drug Facts</b>	
<b>Active ingredient(s)</b>	<b>Purpose</b>
Alcohol 80% 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>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<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>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> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

Non-sterile Solution

**KILLS 99.99% GERMS AND BACTERIAS**



**INSTANT HANDS CLEAN**

**ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION**

<b>Información del Producto</b>
Ingrediente (s) activo Propósito Alcohol 80% v / v ..... Antiséptico.
<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>
<b>Sólo para uso externo. Inflamable. Mantener alejado del calor o llamas.</b>
<b>No utilice</b>
<ul style="list-style-type: none"> <li>• en niños menores de 2 meses de edad</li> <li>• en heridas abiertas de la piel</li> </ul>
<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> Si se ingiere, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.
<b>Direcciones</b>
<ul style="list-style-type: none"> <li>• Coloque suficiente producto en las manos para cubrir todas las superficies. Frotar las manos juntas hasta que se sequen.</li> <li>• Supervise a los niños menores de 6 años cuando use este producto para evitar que se lo traguen.</li> </ul>
<b>Otra información</b>
<ul style="list-style-type: none"> <li>• Almacenar entre 15-30C (59-86F)</li> <li>• Evite la congelación y el calor excesivo por encima de 40C (104F)</li> </ul>
<b>Ingredientes inactivos</b> glicerina, peróxido de hidrógeno, agua purificada USP



Net Weight  
**32 oz (960 ml)**

NDC: 77998-000-05

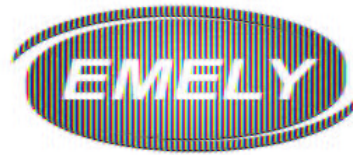


Para comentarios y sugerencias  
Tel.: 809-302-4542  
email.: emiliofigu@hotmail.com  
Elaborado por: Laboratorios E&M  
Santo Domingo, Rep. Dom.  
Reg. Ind. 22054

## Package Label - Principal Display Panel

1,920 mL NDC: 77998-000-06

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 80% v/v	<b>Purpose</b> 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>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

Non-sterile Solution

KILLS 99.99% GERMS AND BACTERIAS



INSTANT HANDS CLEAN

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION



Net Weight  
64 oz (1920 ml)  
NDC: 77998-000-06

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Ingredie  
Alcohol

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Package Label - Principal Display Panel

3,785 mL NDC: 77998-000-07



<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 80% v/v.....	<b>Purpose</b> 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>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP	



# Hand Sanitizer

Non-sterile Solution

**KILLS 99.99% GERMS AND BACTERIAS**



INSTANT HANDS CLEAN

**ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION**

<b>Información del Producto</b>
Ingrediente (s) activo Propósito Alcohol 80% v / v ..... Antiséptico.
<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 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> Si se ingiere, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.
<b>Direcciones</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> glicerina, peróxido de hidrógeno, agua purificada USP



Net Weight  
**128 oz (3,785 ml)**  
NDC: 77998-000-07



Para comentarios y sugerencias  
Tel.: 809-302-4542  
email.: emiliofigu@hotmail.com  
Elaborado por: Laboratorios E&M  
Santo Domingo, Rep. Dom.  
Reg. Ind. 22054

## EMELY HAND SANITIZER

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77998-000
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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:77998-000-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77998-000-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77998-000-03	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
4	NDC:77998-000-04	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
5	NDC:77998-000-05	960 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
6	NDC:77998-000-06	1920 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
7	NDC:77998-000-07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

**Labeler** - Laboratorios E&M SRL (817468959)

### Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios E&M SRL		817468959	manufacture(77998-000)

Revised: 12/2021

Laboratorios E&M SRL