

## **LRV HAND SANITIZER 70% CONSUMER- alcohol gel**

### **LEROLAV HEALTH LLC**

*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:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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 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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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: 78756-413-06



60 mL

Distributed by  
LEROLAV México S.A de C.V.

Made in Mexico

Alcohol Antiseptic 70%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution  
(60 mL)

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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> <b>For external use only. Flammable. Keep away from heat or flame</b>	
<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.	
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<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	

Manufactured for:  
**WWW.LRV.HEALTH**  
LEROLAV HEALTH LLC  
1915 Purdy Ave 2nd Floor Miami Beach  
FL United States of America- 33139

LEROLAV Italia Srl  
Via della Moscova 46/3 Milano,  
Italy - 20121

LEROLAV Mexico S.A. de C.V.  
Sm. 10, Vial 2, LT. 105, House 36, San. Topos Residencial,  
Eclipse Street, Cancun, Q Roo. 77555, Mexico

125 mL NDC: 78756-413-12



125 mL

Distributed by  
LEROLAV México S.A de C.V.

Made in Mexico

Alcohol Antiseptic 70%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution  
(125 mL)

### Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v.....	Antiseptic

### 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

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### Inactive ingredients

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**LEROLAV Italia Srl**  
Via della Moscova 46/3 Milano,  
Italy - 20121

**LEROLAV Mexico S.A. de C.V.**  
Sm. 18, Mzn 2, LT. 105, House 36, Saint Tropez Residential,  
Eclipse Street, Cancun, Q.Roo. 77505, Mexico

250 mL NDC: 78756-413-25



250 mL

Distributed by  
LEROLAV México S.A de C.V.

Made in Mexico

Alcohol Antiseptic 70%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution  
(250 mL)

500 mL NDC: 78756-413-50

## Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v.....	Antiseptic

## 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

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## When using this product

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

## Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Manufactured for:  
**WWW.LRV.HEALTH**

LEROLAV HEALTH LLC  
1215 Pump Ave 2nd Floor Miami Beach  
FL United States of America 33139

LEROLAV Italia Srl  
Via della Mesocora 46/3 Milano,  
Italy - 20121

LEROLAV Mexico S.A. de C.V.  
Srn 16, Mdn 2, Lt 105, House 26, Santa Teresa Residencial,  
Edipe Street, Cancun, Q.Roo, 77020 Mexico



500 mL

Distributed by  
**LEROLAV México S.A de C.V.**  
 Made in Mexico

**Alcohol Antiseptic 70%  
 Topical Solution**

**Hand Sanitizer  
 Non-sterile Solution  
 (500 mL)**

### Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% v/v.....	Antiseptic

### Use(s)

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

### Warnings

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### Do not use

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### Inactive ingredients

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 1815 Pinyan Ave, 2nd Floor, Miami Beach  
 FL, United States of America-33139

**LEROLAV Italia Srl**  
 Via della Moscova 493 Milano,  
 Italy - 20121

**LEROLAV Mexico S.A. de C.V.**  
 Sm 16, Mon 2, LT 105, Herrer 38, Santa Teresa Residencial,  
 Ecoparc Street, Cancun, Q Roo 77505, Mexico

1000 mL NDC: 78756-413-10



1 L

Distributed by  
LEROLAV México S.A de C.V.

Made in Mexico

Alcohol Antiseptic 70%  
Topical Solution

Hand Sanitizer  
Non-sterile Solution  
(1,000 mL)

<b>Drug Facts</b>	
<b>Active ingredient(s)</b> Alcohol 70% 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> <b>For external use only. Flammable. Keep away from heat or flame</b>	
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Sm. 18, Men 2, LT 105, House 36, Santa Tereza Residential,  
Eclipse Street, Cancun, Q.Roo. 77505, Mexico

## LRV HAND SANITIZER 70% CONSUMER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78756-413
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 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:78756-413-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78756-413-12	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78756-413-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78756-413-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78756-413-10	1000 mL in 1 BOTTLE; 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** - LEROLAV HEALTH LLC (131390821)

Revised: 6/2020

LEROLAV HEALTH LLC