

LRV HAND SANITIZER- 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.

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.



125 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
 Topical Solution**

**Antiseptic Hand Rub
 Non-sterile Solution
 (125 mL)**

Manufactured for:
WWW.LRV.HEALTH

LEROLAV HEALTH LLC
 1815 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.
 Sra. 18, Man 2, LT 105, Hoyo 35, Sarg. Tinopol Residencial,
 Edgpool Street, Cancun, Q.Roo 77505, Mexico

Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s)

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP



500 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
Topical Solution**

**Antiseptic Hand Rub
Non-sterile Solution
(500 mL)**

Drug Facts

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Alcohol 80% v/v.....	Antiseptic

Use(s)

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Italy - 20121

LEROLAV Mexico S.A. de C.V.
Sm 18, Mon 2, Lt 105, House 36, Sant Trpez, Residential,
Edipee Street, Cancun, Q.Roo, 77505, Mexico



1 L

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

Made in Mexico

**Alcohol Antiseptic 80%
 Topical Solution**

**Antiseptic Hand Rub
 Non-sterile Solution
 (1,000 mL)**

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use <ul style="list-style-type: none"> • 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.	
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 Italy - 20121

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



60 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
Topical Solution**

**Antiseptic Hand Rub
Non-sterile Solution
(60 mL)**

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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Via della Moscova 46/3 Milano,
Italy - 20121

LEROLAV Mexico S.A. de C.V.
Sitt. 10, Rln 2, Lt. 105, Pkise 30, Sant. Titasac Residential,
Edgese Street, Cancun, Q Roo, 77020 Mexico

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

LRV Hand Sanitizer 60 mL 78756-410-60



60 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
Topical Solution**

**Antiseptic Hand Rub
Non-sterile Solution
(60 mL)**

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> • 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.	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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LEROLAV Mexico S.A. de C.V.
Sitt. 10, Rln 2, Lt. 105, Horse 30, Santa Tereasa Residencial,
Edguate Street, Cancun, Q Roo, 77026 Mexico

LRV Hand Sanitizer 125 mL 78756-410-12



125 mL

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

Made in Mexico

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution
(125 mL)

Manufactured for:
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1815 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.
Sra. 18, Man 2, LT 105, Hoyo 35, Sarg. Tropic Residencial,
Edgose Street, Cancun, Q.Roo 77505, Mexico

Drug Facts

Active ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s)

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP



250 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
 Topical Solution**

**Antiseptic Hand Rub
 Non-sterile Solution
 (250 mL)**

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic
Use(s)	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
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Do not use	
<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 	
When using this product	
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Stop use and ask a doctor	
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Keep out of reach of children.	
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Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	

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 Sm. 18, Man. 2, Lt. 105, House 58, Sant. Topos Residential,
 Eclipse Street, Cancun, Q.Roo. 77505, Mexico

LRV Hand Sanitizer 500 mL 78756-410-50



500 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
Topical Solution**

**Antiseptic Hand Rub
Non-sterile Solution
(500 mL)**

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Via della Moscova 46/3 Milano,
Italy - 20121

LEROLAV Mexico S.A. de C.V.
Sm 18, Mon 2, Lt 105, House 36, Sant Tránsito Residential,
Eduardo Sotelo, Cancun, Q.Roo. 77505 Mexico

LRV Hand Sanitizer 1000 mL 78756-410-10



1 L

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

Made in Mexico

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution
(1,000 mL)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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Italy - 20121

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Sm. 18, Mzn 2, LT 105 House 36, Saint Tropez Residential,
Eclipse Street, Cancun, Q.Roo. 77505 Mexico

LRV HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78756-410
Route of Administration	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: 059QF0K00R)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78756-410-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78756-410-12	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78756-410-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78756-410-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78756-410-10	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