

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) (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 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.

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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: 78756-411-06



60 mL

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

Made in Mexico

Alcohol Antiseptic 70%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution
(60 mL)

Drug Facts	
Active ingredient(s) Alcohol 70% 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.	
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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	

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.
Sm. 18, Mzn 2, LT. 105, House 38, Saint Tizoc Residential,
Eclipse Street, Cancun, Q Roo. 77505 Mexico

125 mL NDC: 78756-411-12



125 mL

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

Made in Mexico

**Alcohol Antiseptic 70%
 Topical Solution**

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

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 46/0 Milano,
 Italy - 20121

LEROLAV Mexico S.A. de C.V.
 Sh. 18, Mch 2 Lt. 105, House 36, Sanit Triplex Residencial,
 Eclipse Street, Cancun, Q Roo. 77500 Mexico

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 70% 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	
<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	
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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	

250 mL NDC: 78756-411-25



250 mL

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

Made in Mexico

Alcohol Antiseptic 70%
 Topical Solution

Antiseptic Hand Rub
 Non-sterile Solution
 (250 mL)

Manufactured for:
WWW.LRV.HEALTH

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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.
 S/n. 18 Uch 2 LT 100, House 36, Saint Tropez Residencial,
 Edipee Street, Cancun, Q.Roo. 77506, Mexico

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% 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 NDC: 78756-411-50



500 mL

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

Made in Mexico

Alcohol Antiseptic 70%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution
(500 mL)

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70% 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.

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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, hydrogen peroxide, purified water USP

Manufactured for:
WWW.LRV.HEALTH

LEROLAV HEALTH LLC
13115 Purity 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.
9th 10, 12th 21, 17 102, House 96, Street Topical, Residencial,
Eclipse Street, Cancun, Q Roo, 77555, Mexico

1000 mL NDC: 78756-411-10



1L

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

Made in Mexico

Alcohol Antiseptic 70%
Topical Solution

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

Drug Facts	
Active ingredient(s) Alcohol 70% 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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Via della Moscova 46/3 Milano,
Italy - 20121

LEROLAV Mexico S.A. de C.V.
Sm. 18, Mzn 2, Lt 105, House 36, Sarril, Tropic Residential,
Eclipse Street, Cancun, Q.Roo. 77505, Mexico

LRV HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78756-411
Route of Administration	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:78756-411-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
2	NDC:78756-411-12	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
3	NDC:78756-411-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
4	NDC:78756-411-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
5	NDC:78756-411-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	

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)

Registrant - LEROLAV HEALTH LLC (131390821)

Revised: 6/2020

LEROLAV HEALTH LLC