

LRV HAND SANITIZER 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.

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.

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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: 78756-412-06



60 mL

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

Made in Mexico

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution
(60 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 463 Milano,
Italy - 20121

LEROLAV Mexico S.A. de C.V.
Sm. 18, Man 2, Lt 105, House 30, Sanit Topoz Residential,
Edifice Street Cancun, Q Roo 77029, Mexico

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% 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	
<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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if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children.	
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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	

125 mL NDC: 78756-412-12



125 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
 Topical Solution**

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

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% 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	
<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	

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 Mescola 469 Milano,
 Italy - 20121

LEROLAV Mexico S.A. de C.V.
 Sm. 18, Mon 2 LT 125, House 36, Saint Tropez Residencial,
 Ecatepec Street, Cancun, Q Roo. 77500 Mexico

250 mL NDC: 78756-412-25



250 mL

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

Made in Mexico

**Alcohol Antiseptic 80%
 Topical Solution**

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

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% 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	
<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	

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.
 S/n, 18, Man 2 Lt, 105, House 36, Saint Tizoc Residential,
 Eclipse Street, Cancun, Q.Roo. 77505, Mexico

500 mL NDC: 78756-412-50



500 mL

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

Made in Mexico

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution
(500 mL)

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% 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	
<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	

Manufactured for:
WWW.LRV.HEALTH

LEROLAV HEALTH LLC
1815 Purity Ave 3rd 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 16, Nivel 2, Lt 105, Haces 96, Carr: Tijuca Residencial,
Eclipse Street, Cancun, Q Roo, 77505, Mexico

1000 mL NDC: 78756-412-10



1 L

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

Made in Mexico

Alcohol Antiseptic 80%
Topical Solution

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

Drug Facts	
Active ingredient(s) Alcohol 80% v/v.....	Purpose 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 <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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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	

Manufactured for:
WWW.LRV.HEALTH

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1315 Purity Ave. 2nd Floor, Miami Beach
FL, United States of America- 33139

LEROLAV Italia Srl
Via delle Moscove 463 Milano,
Italy - 20121

LEROLAV Mexico S.A. de C.V.
Sm. 16, Mtn 2, Lt. 105, House-36, Sanit Tropes Residential,
Edipse Street, Cancun, Q Roo. 77506, Mexico

LRV HAND SANITIZER CONSUMER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78756-412
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:78756-412-06	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78756-412-12	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78756-412-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78756-412-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78756-412-10	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