

HAND SANITIZER- alcohol gel
Lubri-Lab Mx, S.A. de C.V.

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 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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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

LADSI


Hand Sanitizer



Kills 99.99% germs and bacteria. Without rinsing

**»Antibacterial
»Desinfectant
»Antiseptic
»Sanitizer**

8.79 OZ FL (250 ml)

Drug Facts	LADSI
Active ingredients	Purpose
Ethyl Alcohol 70 % v/v.....	Antiseptic
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 of flame. Do not use on children less than 2 months of age and 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:	
Rub hands together for at least 20 sec. Supervise children under 6 years of age when using this product to avoid swallowing.	
Inactive ingredients:	
Water, triethanolamine, carbomer, glycerine	
Manufactured to specifications of the Secretaria de Salud y COFEPRIS: agreement of 22/12/2014 DOF NOM-138-SSA-2016 FDA 3013570450	
Made by: LUBRI LAB MX S.A de C.V Parque Ind. Apolo Irapuato, Gto., MX. www.lubrilabmx.com	
UPC	
	
7502226780856	

Hand Sanitizer

Kills 99.99% of germs

169.07 OZ FL (5 L)

059 mL NDC: 77181-002-02

5000 mL NDC: 77181-002-50

5000 mL NDC: 77181-002-50

250 mL NDC: 77181-003-08

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic
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 of flame.	
Do not use:	
<ul style="list-style-type: none"> - In children less than 2 months of age - On open skin wounds. 	
When using / Stop use / keep out of reach of children:	
<ul style="list-style-type: none"> - 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 surface. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.	
Other Information	
Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F).	
Inactive Ingredients	
Water, Triethanolamine, Carbomer, Glycerine.	

Effective at eliminating more than 99.99% of many common harmful germs.
Product distributed by Home Kare Products, Inc.
3755 Harlem Road
Buffalo, NY. 14215, USA
FDA 3013570450 registration for
LUBRI-LAB MX, SA DE CV Made in Mexico

(Lot)
00000000

Expiration date
mm/yyyy



UPC - BARCODE

Hand Sanitizer

Kills 99.99% of germs

2 OZ FL (59.1 mL)

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antiseptic
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 of flame.	
Do not use:	
- In children less than 2 months of age	
- On open skin wounds.	
When using / Stop use / keep out of reach of children:	
- 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 surface. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.	
Other Information	
Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104F).	
Inactive Ingredients	
Water, Triethanolamine, Carbomer, Glycerine.	

Effective at eliminating more than 99.99% of many common harmful germs.

Product distributed by Home Kare Products, Inc.

3755 Harlem Road

Buffalo, NY, 14215, USA

FDA 3013570450 registration for

LUBRI-LAB MX, SA DE CV

Made in Mexico

(Lot)
000000
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UPC

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7718 1-002
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:77181-002-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77181-002-50	5000 mL in 1 BOTTLE, PUMP; 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	

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77181-003
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:77181-003-08	250 mL in 1 BOTTLE, PUMP; 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 - Lubri-Lab Mx, S.A. de C.V. (813500519)

Registrant - Lubri-Lab Mx, S.A. de C.V. (813500519)

Establishment

Name	Address	ID/FEI	Business Operations
Lubri-Lab Mx, S.A. de C.V.		813500519	manufacture(77181-002, 77181-003)

Revised: 7/2020

Lubri-Lab Mx, S.A. de C.V.