

HAND SANITIZER- alcohol spray
Comercializadora Lopaza, 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.

Hand Sanitizer

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) (75%, 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 75% 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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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

PERSONAL CARE
M3GA CLEAN
NATURAL & PRESCRIPTION FORMULAS
TOPICAL SOLUTION

Spray

ANTI-Virus & Bacteria
KILLS 99.9% OF ALL GERMS

Recommended for Disinfects hands and objects

**75% Ethyl Alcohol
HAND SANITIZER**

WARNING FLAMMABLE Keep away from heat, spark, electrical, fire or flame

2.53 FL OZ (75mL)

Drugs Facts	
Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water	
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 surface. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing	
Other Information ■ Store between 16-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.	

PRODUCT OF MEXICO

Imported by:
Dist. de Prod. Alim. el Paisita
4712 N 12Th St Suite 47
McAllen TX. 78504
Phone 956-438-5436

Manufactured by:
Comercializadora Lopza S.A. de C.V.
Profesor Celso Flores No. 435
Guadalupe N.L. 67110
Tel: (81)82996631
www.lopza.com



Labeler code 78722

75 mL NDC: 78722-124-01

Package Label - Principal Display Panel

PERSONAL CARE
M3GA CLEAN
NATURAL'S PRESCRIPTION FOR THE HOME

TOPICAL SOLUTION

Spray

**-ANTI-
Virus & Bacterias
KILLS 99.9% OF ALL GERMS**

Recommended for Disinfects hands and objects

**75% Ethyl Alcohol
HAND SANITIZER**

WARNING FLAMMABLE **Keep away from heat, spark,
electrical, fire or flame**

33.81 FL OZ (1000 mL)

1000 mL NDC: 78722-124-02

Package Label - Principal Display Panel

Drugs Facts

Active Ingredient

Ethyl alcohol 75% v/v.....Antiseptic

Purpose

Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water

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 surface. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing

Other Information

■ Store between 16-30C (59-86F)

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

Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.

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Spray

-ANTI-
Virus & Bacteria
KILLS 99.9% OF ALL GERMS

Recommended for Disinfects hands and objects

75% Ethyl Alcohol
HAND SANITIZER



169.07 FL OZ (5000 mL)

5000 mL NDC: 78722-124-03

Package Label - Principal Display Panel

Drugs Facts

Active Ingredient

Ethyl alcohol 75% v/v.....Antiseptic

Purpose

Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water

Warnings

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Flammable, Keep away from heat or flame

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Other Information

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

Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.

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Labeler code 78722



Spray

-ANTI-
Virus & Bacteria
KILLS 99.9% OF ALL GERMS

Recommended for Disinfects hands and objects

75% Ethyl Alcohol HAND SANITIZER



1690.70 FL OZ (50000 mL)

50000 mL NDC: 78722-124-05

Package Label - Principal Display Panel

Drugs Facts

Active Ingredient

Ethyl alcohol 75% v/v.....Antiseptic

Purpose

Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water

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

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Directions

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- Supervise children under 6 years of age when using this product to avoid swallowing

Other Information

■ Store between 16-30C (59-86F)
Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.

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Labeler code 78722



Spray

-ANTI-
Virus & Bacteria
KILLS 99.9% OF ALL GERMS

Recommended for Disinfects hands and objects

75% Ethyl Alcohol HAND SANITIZER

WARNING
FLAMMABLE



Keep away from heat, spark,
electrical, fire or flame

6762.80 FL OZ (200000 mL)

Drugs Facts

Active Ingredient

Ethyl alcohol 75% v/v.....Antiseptic

Purpose

Uses ■ Hand Sanitizer to help reduce bacteria that potentially can cause disease. ■ For use when soap and water

Warnings

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HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78722-124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 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:78722-124-01	75 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78722-124-02	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78722-124-03	5000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78722-124-04	200000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78722-124-05	50000 mL in 1 BOTTLE, SPRAY; 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 - Comercializadora Lopaza, S.A. de C.V. (812293143)

Registrant - Mario Hidalgo (080666336)

Establishment			
Name	Address	ID/FEI	Business Operations
Comercializadora Lopaza, S.A. de C.V.		812293143	manufacture(78722-124)