

HAND SANITIZER- alcohol gel
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

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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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, carbomer 940, Trolamine, purified water USP

Package Label - Principal Display Panel

PERSONAL CARE
**M3GA
CLEAN**
NATURE'S PRESCRIPTION FOR SHINE

Alcohol Antiseptic
75% Ethyl Alcohol GEL
Topical Solution
Hand Sanitizer

2.53 FL OZ (75 mL)

Drugs Facts

Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ 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 surface. Rub hands together until dry. ■ Supervise children under 6 years of age when using this product to avoid swallowing	
Other Information ■ Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients Glycerin, Carbomer 940, Trolamine, Purified water.	

PRODUCT OF MEXICO

Labeler code 78722

Imported by:
Dist. de Prod. Alim. el Paisita
4712 N 12th St Suite 47
McAllen TX, 78504
Phone 956-436-5436

Manufactured by:
Comercializadora Lopez S.A. de C.V.
Profesor Celso Flores No. 435
Guadalupe Nuevo Leon Mexico
67110 Ph +52(81)82996631
www.lopeza.mx

7 15 0 3 0 3 0 1 2 2 4 1 3 0

75 mL NDC: 78722-123-01

Package Label - Principal Display Panel

50000 mL NDC: 78722-123-05

PERSONAL CARE
**M3GA
CLEAN**
NATURE'S PRESCRIPTION FOR SHINE

Alcohol Antiseptic
75% Ethyl Alcohol GEL
Topical Solution
Hand Sanitizer

1690.70 FL OZ (50000 mL)

Drugs Facts

Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ 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	
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7 15 0 3 0 3 0 1 2 2 4 1 3 0

Package Label - Principal Display Panel



PERSONAL CARE
**M3GA
CLEAN**
NATURE'S PRESCRIPTION FOR SHINE

Alcohol Antiseptic
75% Ethyl Alcohol GEL
Topical Solution
Hand Sanitizer

33.81 FL OZ (1000 mL)

1000 mL NDC: 78722-123-02

Drugs Facts	
Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ 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 surface. Rub hands together until dry.	
■ Supervise children under 6 years of age when using this product to avoid swallowing	
Other Information ■ Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients	
Glycerin, Carbomer 940, Trolamine, Purified water.	

PRODUCT OF MEXICO



Imported by:
Dist. de Prod. Alim. el Pastita
4712 N 12th St Suite 47
McAllen TX, 78504
Phone 056-430-5436

Labeler code 78722

Manufactured by:
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www.lopezsa.mx

Package Label - Principal Display Panel



PERSONAL CARE
**M3GA
CLEAN**
NATURE'S PRESCRIPTION FOR SHINE

Alcohol Antiseptic
75% Ethyl Alcohol GEL
Topical Solution
Hand Sanitizer

169.07 FL OZ (5000 mL)

5000 mL NDC: 78722-123-03

Drugs Facts	
Active Ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic
Uses ■ 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	
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Other Information ■ Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients	
Glycerin, Carbomer 940, Trolamine, Purified water.	

PRODUCT OF MEXICO



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Package Label - Principal Display Panel



Alcohol Antiseptic
75% Ethyl Alcohol GEL
 Topical Solution
Hand Sanitizer

6762.80 FL OZ (200000 mL)

200000 mL NDC: 78722-123-04

Drugs Facts

Active Ingredient

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

Purpose

Uses ■ 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.

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

Inactive ingredients

Glycerin, Carbomer 940, Trolamine, Purified water.

PRODUCT OF MEXICO



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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78722-123
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
CARBOMER 940 (UNII: 4Q93RCW27E)	0.75 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78722-123-01	75 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78722-123-02	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

3	NDC:78722-123-03	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78722-123-04	200000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78722-123-05	50000 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 - 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(78722-123)

Revised: 6/2020

Comercializadora Lopaza, S.A. de C.V.