

HAND SANITIZER- alcohol gel

Jorge Martin Gomez Sanchez

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) (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. Sterile distilled water or boiled cold water.
- c. Isopropyl Alcohol
- d. Carbomer 940
- e. Glycerin
- f. Triethanolamine
- g. Aloe Vera Leaf extract.

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.

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

Purified water USP, isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera extract.

Package Label - Principal Display Panel

1000 mL NDC: 78471-005-01

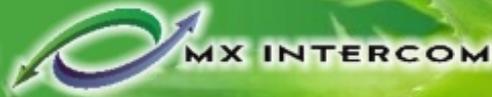


HAND SANITIZER
STAY CLEAN STAY SAFE

Kill 99.99% of harmful germs
moisturizes with aloe vera



NET WT. 33.8 fl oz (1L)



MEX LABS
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts	
Active Ingredients	Purpose:
Ethyl Alcohol 70%.....	Antiseptic
Use	
For handwashing to decrease bacteria on the skin Recommended for repeated use	
Warnings:	
For external use only Flammable keep away from fire or flame In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	
Directions:	
Receive a small amount of liquid into palm of hand Rub hands together until dry Rub thoroughly over all surfaces of both hands	
Other information:	
Store in a cool dry place below 104° F	
Inactive Ingredients :	
Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe Vera Extract	



0 732535 913011
Exp: April 2022
Lot:20042001GA
MADE IN MEXICO

70% ALCOHOL

Distributed by
CONNECT E. LLC
1372 Vintage Pointe Dr.
Lawrenceville, Ga 30044

Elaborated by:
Jorge Martín Gómez Sanchez
Av. Santa Croce No. 115-C
C.P. 37439 León Gto.
mxintercom@gmail.com

33.8 fl oz (1L)

3780 mL NDC: 78471-005-02



HAND SANITIZER
STAY CLEAN STAY SAFE

**Kill 99.99% of
harmful germs**
**moisturizes
with aloe vera**



NET WT. 1 Gallón. / 3.78 L



MEX LABS
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients	Purpose:
Ethyl Alcohol 70%.....	Antiseptic

Use
For handwashing to decrease bacteria on the skin
Recommended for repeated use

Warnings:
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Flammable keep away from fire or flame
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Directions:
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Rub thoroughly over all surfaces of both hands

Other information:
Store in a cool dry place below 104° F

Inactive Ingredients :
Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine,
Aloe Vera Extract



0 732535 913028
Exp: April 2022
Lot:20042001GA
MADE IN MEXICO

**70%
ALCOHOL**

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1 Gallón. / 3.78 L

5000 mL NDC: 78471-005-03



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NET WT. 1.33 Gallons. 5 L



MEX LABS
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts	
Active Ingredients	Purpose:
Ethyl Alcohol 70%.....	Antiseptic
Use	
For handwashing to decrease bacteria on the skin Recommended for repeated use	
Warnings:	
For external use only Flammable keep away from fire or flame In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	
Directions:	
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Inactive Ingredients :	
Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe Vera Extract	



0 732535 913035
Exp: April 2022
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1.33 Gallons. 5 L

19000 mL NDC: 78471-005-04

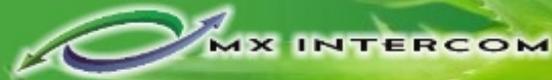


HAND SANITIZER
STAY CLEAN STAY SAFE

Kill 99.99% of harmful germs
moisturizes with aloe vera



NET WT. 5.01 Gallons / 19 L



MEX LABS
TOTAL CARE

Hand Sanitizer Gel
With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts	
Active Ingredients	Purpose:
Ethyl Alcohol 70%.....	Anticaptic
Use For handwashing to decrease bacteria on the skin Recommended for repeated use	
Warnings: For external use only Flammable keep away from fire o flame In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	
Directions: Receive a small amount of liquid into palm of hand Rub hands together until dry Rub thoroughly over all surfaces of both hands	
Other information: Store in a cool dry place below 104° F	
Inactive Ingredients : Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe Vera Extract	



0 732535 913042
Exp: April 2022
Lot:20042001GA
MADE IN MEXICO

70% ALCOHOL

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Lawrenceville, Ga 30044

Elaborated by:
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5.01 Gallons 19 L

120 mL NDC: 78471-005-05

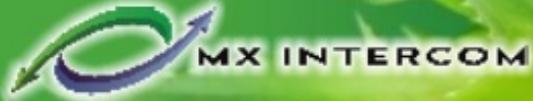


HAND SANITIZER
STAY CLEAN STAY SAFE

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moisturizes with aloe vera



NET WT. 4.05 fl oz. (120 mL)



MEX LABS

TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients Purpose:
Ethyl Alcohol 70%..... Antiseptic

Use
For handwashing to decrease bacteria on the skin
Recommended for repeated use

Warnings:
For external use only
Flammable keep away from fire or flame
In case of accidental ingestion, seek medical attention or contact a poison control center immediately.

Directions:
Receive a small amount of liquid into palm of hand
Rub hands together until dry
Rub thoroughly over all surfaces of both hands

Other information:
Store in a cool dry place below 104° F

Inactive Ingredients :
Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe Vera Extract



0 732535 912984
Exp: April 2022
Lot:20042001GA

MADE IN MEXICO

70% ALCOHOL

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Lawrenceville, Ga 30044

Elaborated by:
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4.05 fl oz. (120 mL)

250 mL NDC: 78471-005-06



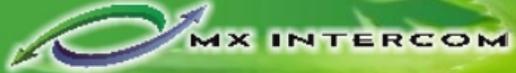
HAND SANITIZER
STAY CLEAN STAY SAFE

**Kill 99.99% of
harmful germs**

**moisturizes
with aloe vera**



NET WT. 8.45 fl oz. (250 ml)



MEX LABS

TOTAL CARE

**Hand
Sanitizer Gel**

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients	Purpose:
Ethyl Alcohol 70%	Antiseptic

Use
For handwashing to decrease bacteria on the skin
Recommended for repeated use

Warnings:
For external use only
Flammable keep away from fire or flame
In case of accidental ingestion, seek medical attention
or contact a poison control center immediately.

Directions:
Receive a small amount of liquid into palm of hand
Rub hands together until dry
Rub thoroughly over all surfaces of both hands

Other information:
Store in a cool dry place below 104° F

Inactive Ingredients :
Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine,
Aloe Vera Extract



0 732535 912991
Exp: April 2022
Lot:20042001GA
MADE IN MEXICO

**70%
ALCOHOL**

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Lawrenceville, Ga 30044

Elaborated by:
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8.45 fl oz (250 mL)

500 mL NDC: 78471-005-07

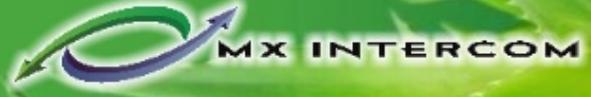


HAND SANITIZER
STAY CLEAN STAY SAFE

Kill 99.99% of harmful germs
moisturizes with aloe vera



NET WT. 16.9 fl oz (500 mL)



MEX LABS
TOTAL CARE

Hand Sanitizer Gel
With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts	
Active Ingredients Ethyl Alcohol 70%.....	Purpose: Antiseptic
Use For handwashing to decrease bacteria on the skin Recommended for repeated use	
Warnings: For external use only Flammable keep away from fire or flame In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	
Directions: Receive a small amount of liquid into palm of hand Rub hands together until dry Rub thoroughly over all surfaces of both hands	
Other information: Store in a cool dry place below 104° F	
Inactive Ingredients : Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe Vera Extract	



70% ALCOHOL

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CONNECT E. LLC
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Elaborated by:
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C.P. 37439 León Gto.
mxintercom@gmail.com

Exp: April 2022
Lot:20042001GA
MADE IN MEXICO

16.9 fl oz (500 mL)

100000 mL NDC: 78471-005-08



HAND SANITIZER

STAY CLEAN STAY SAFE

Kill 99.99% of harmful germs

moisturizes with aloe vera



NET WT. 264.1 Gallons / 1,000 L



MEX LABS

TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXXX-XX

Drug Facts	
Active Ingredients	Purpose:
Ethyl Alcohol 70%.....	Antiseptic
Use	
For handwashing to decrease bacteria on the skin Recommended for repeated use	
Warnings:	
For external use only Flammable keep away from fire or flame In case of accidental ingestion, seek medical attention or contact a poison control center immediately.	
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Other information:	
Store in a cool dry place below 104° F	
Inactive Ingredients :	
Water, Isopropyl Alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe Vera Extract	



70% ALCOHOL

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264.1 Gallons 1,000 L

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78471-005
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
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	
TRIETHANOLAMINE TRIS(DIHYDRO GEN PHOSPHATE) (UNII: 36YHT392ID)	
GLYCERIN (UNII: PDC6A3C0OX)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78471-005-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78471-005-02	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78471-005-03	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78471-005-04	19000 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78471-005-05	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78471-005-06	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78471-005-07	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78471-005-08	1000000 mL in 1 DRUM; 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 - Jorge Martin Gomez Sanchez (951577703)

Establishment

Name	Address	ID/FEI	Business Operations
Jorge Martin Gomez Sanchez		951577703	manufacture(78471-005)

Revised: 8/2020

Jorge Martin Gomez Sanchez