

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
- c. Isopropyl alcohol
- d. Carbomer 940
- e. Glycerin
- f. Triethanolamine
- g. Aloe vera Leaf

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

Water, isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera leaf

Package Label - Principal Display Panel

33.8 fl oz Hand sanitizer NDC 78471-001-01

Franche Lab[®]
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol70%

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 Ingredient:

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

Elaborated by:

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MADE IN MEXICO



**70%
ALCOHOL**

Exp: April 2022
Lot:20042001GA

33.8 fl oz
1 L

16.9 fl oz Hand sanitizer NDC 78471-001-02

Franche Lab[®]
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol70%

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 Ingredient:

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

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MADE IN MEXICO

**70%
ALCOHOL**



Exp: April 2022
Lot:20042001GA

16.9 fl oz
500 mL

8.4 fl oz Hand sanitizer NDC 78471-001-03

Franche Lab®
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol 70%

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 Ingredient:

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

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MADE IN MEXICO

**70%
ALCOHOL**



Exp: April 2022
Lot:20042001GA

8.4 fl oz
250 mL

4 fl oz Hand sanitizer NDC 78471-001-04

Franche Lab[®]
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol 70%

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 Ingredient

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

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MADE IN MEXICO

**70%
ALCOHOL**



Exp: April 2022
Lot:20042001GA

4 fl oz
120 mL

1 Gallon Hand sanitizer NDC 78471-001-05

Franche Lab[®]
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol70%

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 Ingredient:

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

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MADE IN MEXICO



**70%
ALCOHOL**

Exp: April 2022
Lot:20042001GA

1 Gallon
3.8 L

1.5 Gallon Hand sanitizer NDC 78471-001-06

Franche Lab[®]
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts	
Active Ingredients	
Ethyl Alcohol	70%
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 Ingredient	
Water, Isopropyl alcohol, Carbomer 940, Glycerin, Triethanolamine, Aloe vera extract.	

Elaborated by:

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MADE IN MEXICO



**70%
ALCOHOL**

Exp: April 2022
Lot:20042001GA

1.5 Gallon
5 L

5 Gallons Hand sanitizer NDC 78471-001-07

Franche Lab[®]
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol70%

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 Ingredient

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

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MADE IN MEXICO



**70%
ALCOHOL**

Exp: April 2022
Lot:20042001GA

5 Gallons
19 L

300.2 Gallon Hand sanitizer NDC 78471-001-08

franche Lab®
TOTAL CARE

Hand Sanitizer Gel

With Aloe Vera and Glycerine

NDC - XXXXX-XXX-XX

Drug Facts

Active Ingredients

Ethyl Alcohol70%

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 Ingredient

Water, Isopropyl alcohol, Carbomer 940, Glycerin,
Triethanolamine, Aloe vera extract.

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MADE IN MEXICO



**70%
ALCOHOL**

Exp: April 2022
Lot:20042001GA

300.2 Gallons
1000 L

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78471-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name				Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
WATER (UNII: 059QF0KO0R)				
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78471-001-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78471-001-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78471-001-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78471-001-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78471-001-05	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78471-001-06	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78471-001-07	19000 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78471-001-08	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(78471-001)

Revised: 6/2020

Jorge Martin Gomez Sanchez