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



Hand Sanitizer Gel

With Aloe Vera and Glycerine

Drug Facts

Ethyl Alcohol .

Active Ingredients

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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:

Jorge Martín Gómez Sanchez Av. Santa Crocce No. 115-C C.P. 37439 León Gto. Info@franchelab.com.mx



70% ALCOHOL

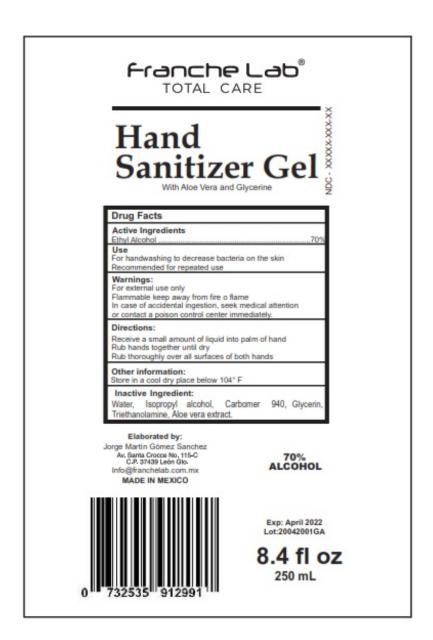
Exp: April 2022 Lot:20042001GA

33.8 fl oz

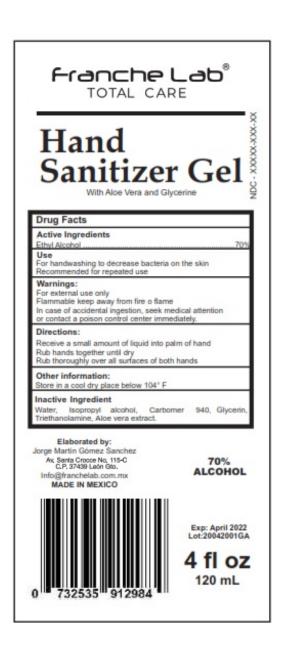
1 L



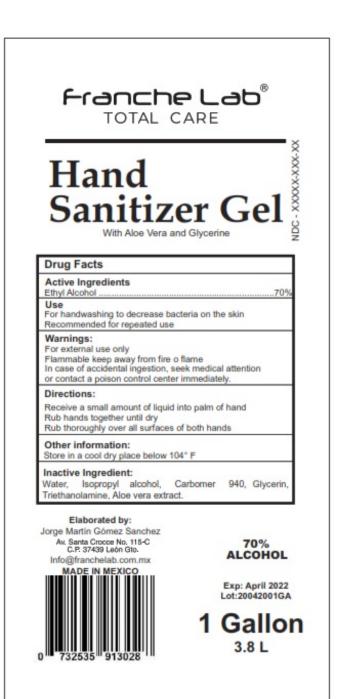
8.4 fl oz Hand sanitizer NDC 78471-001-03



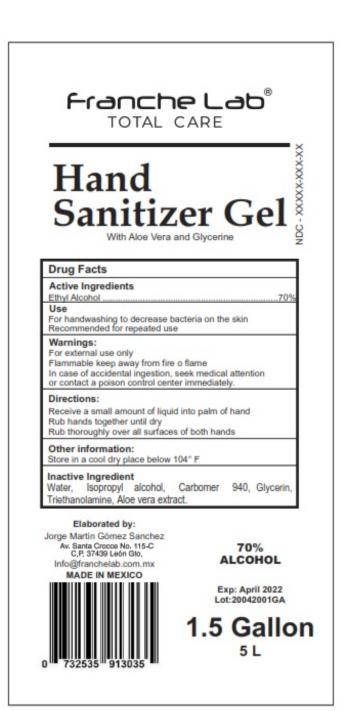
4 fl oz Hand sanitizer NDC 78471-001-04



1 Gallon Hand sanitizer NDC 78471-001-05



1.5 Gallon Hand sanitizer NDC 78471-001-06



5 Gallons Hand sanitizer NDC 78471-001-07



Hand Sanitizer Gel

With Aloe Vera and Glycerine

Drug F	acts
	Ingredients ohol
	lwashing to decrease bacteria on the skin nended for repeated use
Flamma In case	gs: rnal use only ole keep away from fire o flame of accidental ingestion, seek medical attention ct a poison control center immediately.
Rub han	ns: a small amount of liquid into palm of hand ds together until dry oughly over all surfaces of both hands
	nformation: a cool dry place below 104° F
Water,	Ingredient Isopropyl alcohol, Carbomer 940, Glycerin, olamine, Aloe vera extract.

Elaborated by:

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70% ALCOHOL

Exp: April 2022 Lot:20042001GA

5 Gallons

300.2 Gallon Hand sanitizer NDC 78471-001-08



Hand Sanitizer Gel Hand

With Aloe Vera and Glycerine

Drug Facts	
Active Ingredients Ethyl Alcohol	70%
Use For handwashing to decrease bacteria on the skir Recommended for repeated use	n
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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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

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

I	Ingredient Name	Basis of Strength	Strength
I	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
WATER (UNII: 059QF0KO0R)		
TRIETHANO LAMINE TRIS(DIHYDRO GEN PHO SPHATE) (UNII: 36 YHT392ID)		
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