

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 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.

500 mL NDC: 78471-004-02

HAND SANITIZER GEL



sterling
pacific

KILLS
99%
of most common
germs that may
cause illness



ALCOHOL ANTISEPTIC

ALCOHOL
70%



WITH ALOE VERA

Net. Content: 16.9 fl oz (500 ml)

Drug Facts

ACTIVE INGREDIENTS:

PURPOSE:

Ethyl alcohol 70%Antiseptic

Uses:

To help decrease bacteria on the skin
Recommended for repeated use.

Warnings:

For external use only.

Flammable. Keep away from fire or flame.

Keep out of eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.

Avoid contact with broken skin.

Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.

Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

Place small amount of sanitizer in your palm.
Thoroughly spread on both hand and rub together until dry.

Other information:

Store below 105 °F

May discolor some fabrics

Inactive ingredients: Water, isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera extract.

Manufacture by:

Jorge Martín Gómez Sánchez
Av. Santa Croce #115 C. León, Gto C.P. 37439, México
info@franchelab.com.mx

Distributed by:

Production Partners Chemical Co. Inc. 1223 Sherborn St. Bldg. 101
Corona, CA 92879 PH (951) 808-0600 Ext. 223



0 732535 913004

NDC: XXXXX-XXX-XX

Lot:
Expiration:

1000 mL NDC: 78471-004-03

HAND SANITIZER GEL



sterling
pacific

KILLS
99%
of most common
germs that may
cause illness



ALCOHOL ANTISEPTIC

ALCOHOL
70%



WITH ALOE VERA

Net. Content: 33.8 fl oz (1000 ml)

Drug Facts

ACTIVE INGREDIENTS:

PURPOSE:

Ethyl alcohol 70%Antiseptic

Uses:

To help decrease bacteria on the skin
Recommended for repeated use.

Warnings:

For external use only.

Flammable. Keep away from fire or flame.

Keep out of eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.

Avoid contact with broken skin.

Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.

Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

Place small amount of sanitizer in your palm.
Thoroughly spread on both hand and rub together until dry.

Other information:

Store below 105 °F

May discolor some fabrics

Inactive ingredients: Water, isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera extract.

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0 732535 913004

NDC: XXXXX-XXX-XX

Lot:
Expiration:

3800 mL NDC: 78471-004-04

HAND SANITIZER GEL



sterling
pacific

KILLS
99%
of most common
germs that may
cause illness



ALCOHOL ANTISEPTIC

ALCOHOL
70%



WITH ALOE VERA

Net. Content: 1 gal (3.8 lts)

Drug Facts

ACTIVE INGREDIENTS:

PURPOSE:

Ethyl alcohol 70%Antiseptic

Uses:

To help decrease bacteria on the skin
Recommended for repeated use.

Warnings:

For external use only.

Flammable. Keep away from fire or flame.

Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.

Avoid contact with broken skin.

Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.

Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

Place small amount of sanitizer in your palm. Thoroughly spread on both hand and rub together until dry.

Other information:

Store below 105 °F

May discolor some fabrics

Inactive ingredients: Water Isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera extract.

Manufacture by:

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Corona, CA 92679 PH (951) 808-0600 Ext. 223



0 732535 913004

NDC: XXXXX-XXX-XX

Lot:
Expiration:

19000 mL NDC: 78471-004-05

HAND SANITIZER GEL



sterling
pacific

KILLS
99%
of most common
germs that may
cause illness



ALCOHOL ANTISEPTIC

ALCOHOL
70%



WITH ALOE VERA

Net. Content: 5 gal (19 lts)

Drug Facts

ACTIVE INGREDIENTS:

PURPOSE:

Ethyl alcohol 70%Antiseptic

Uses:

To help decrease bacteria on the skin
Recommended for repeated use.

Warnings:

For external use only.

Flammable. Keep away from fire or flame.

Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately.

Avoid contact with broken skin.

Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs.

Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.

Direction:

Place small amount of sanitizer in your palm. Thoroughly spread on both hand and rub together until dry.

Other information:

Store below 105 °F

May discolor some fabrics

Inactive ingredients: Water Isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera extract.

Manufacture by:

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Corona, CA 92679 PH (951) 808-0600 Ext. 223



0 732535 913004

NDC: XXXXX-XXX-XX

Lot:
Expiration:

1000000 mL NDC: 78471-004-06

HAND SANITIZER GEL



sterling
pacific

KILLS
99%
of most common
germs that may
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ALCOHOL ANTISEPTIC

ALCOHOL
70%



WITH ALOE VERA

Drug Facts
ACTIVE INGREDIENTS:
PURPOSE: Ethyl alcohol 70%Antiseptic
Uses: To help decrease bacteria on the skin Recommended for repeated use.
Warnings: For external use only. Flammable. Keep away from fire or flame. Keep out eyes. In case of eye contact, flush it thoroughly with water, seek medical attention immediately. Avoid contact with broken skin. Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hrs. Keep away from children. If swallowed, seek medical attention immediately. Children must only use this product under adult supervision.
Directions: Place small amount of sanitizer in your palm. Thoroughly spread on both hand and rub together until dry.
Other information: Store below 105 °F May discolor some fabrics
Inactive ingredients: Water, isopropyl alcohol, carbomer 940, glycerin, triethanolamine, aloe vera extract.

NDC: XXXXX-XXX-XX

Manufacture by:
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Distributed by:
Production Partners Chemical Co. Inc. 1223 Sherborn St. Bldg. 101
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Lot:
Expiration:

Net. Content: 264.1 gal (1000 lts)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78471-004
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78471-004-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78471-004-02	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78471-004-03	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78471-004-04	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78471-004-05	19000 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78471-004-06	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(78471-004)