

HAND SANITIZER- alcohol gel

Jorge Martín 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. Triethalonamine
- 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.

120 mL NDC: 78471-003-02

Franche Lab®
TOTAL CARE

Kills
99%
of most common
germs that may
cause illness



GEL
HAND SANITIZER



WITH ALOE VERA

70%
Alcohol

Alcohol Antiseptic

Net. Content: 4.05 FL OZ (120 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: CAPITAL MARKETING
ASSOCIATES, INC.



0 732535 913110

NDC: XXXXX-XXX-XX

Lot:
Expiration:

250 mL NDC: 78471-003-03

Franche Lab®
TOTAL CARE

Kills
99%
of most common
germs that may
cause illness



GEL
HAND SANITIZER



WITH ALOE VERA

70%
Alcohol

Alcohol Antiseptic

Net. Content: 8.4 FL OZ (250 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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ASSOCIATES, INC.



0 732535 913073

NDC: XXXXX-XXX-XX

Lot:
Expiration:

500 mL NDC: 78471-003-04

Franche Lab[®]
TOTAL CARE

GEL

HAND SANITIZER



70%
Alcohol

Alcohol Antiseptic

Net. Content: 16.9 FL OZ (500 ML)

Kills
99%
of most common
germs that may
cause illness



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:

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0 732535 913127

NDC: XXXXX-XXX-XX

Lot:
Expiration:

1000 mL NDC: 78471-003-05

Franche Lab[®]
TOTAL CARE

GEL

HAND SANITIZER



70%
Alcohol

Alcohol Antiseptic

Net. Content: 33.8 FL OZ (1000 ML)

Kills
99%
of most common
germs that may
cause illness



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

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Distributed by: CAPITAL MARKETING
ASSOCIATES, INC.



0 732535 913080

NDC: XXXXX-XXX-XX

Lot:
Expiration:

5000 mL NDC: 78471-003-06

Franche Lab[®]
TOTAL CARE

Kills
99%
of most common
germs that may
cause illness



GEL
HAND SANITIZER



WITH ALOE VERA

70%
Alcohol

Alcohol Antiseptic

Net. Content: 169 FL OZ (5000 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

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info@franchelab.com.mx

Distributed by: CAPITAL MARKETING
ASSOCIATES, INC.



0 732535 913103

NDC: XXXXX-XXX-XX

Lot:
Expiration:

HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78471-003 |
| 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 |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| WATER (UNII: 059QF0K00R) | |
| TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |

| Packaging | | | | |
|-------------------------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:78471-003-01 | 3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:78471-003-02 | 120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:78471-003-03 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:78471-003-04 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 5 | NDC:78471-003-05 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 6 | NDC:78471-003-06 | 5000 mL in 1 BOTTLE, PLASTIC; 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 Martín Gomez Sanchez (951577703)

| Establishment | | | |
|----------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Jorge Martín Gomez Sanchez | | 951577703 | manufacture(78471-003) |