

HAND SANITIZER- alcohol gel

Magaña Muela, Jesús

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

Active Ingredient(s)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, 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. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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.

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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

Distilled water, glycerin, carbomer 940, Trolamine

Package Label - Principal Display Panel



3785 mL NDC 77934-123-11

Package Label - Principal Display Panel

Drug Facts	
Active ingredient Ethyl alcohol 75% v/v.....	Purpose Antiseptic
Uses (s) Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.	
Warnings ----- For external use only. Flammable. Keep away from heat or flame.	
Do not use; - On 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 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 Poison Control Center right away.	
Directions - Place enough product on hands over 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 15-30 °C (59-86 °F) - Avoid freezing and excessive heat above 40 °C (104 °F)	
Inactive ingredients Distilled water, Glycerin, Carbomer 940, Trolamine.	
MADE IN MEXICO Distributed by: Supreme foods 2000w 34th St., Chicago Il. 60608 Email: info@mysupremefoods.com	
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HAND SANITIZER



Moisturizing Gel

75% ETHYL ALCOHOL

WARNING  **FLAMMABLE** | Keep away from heat, spark, electrical, fire or flame

4.2 FL OZ (125 mL)

125 mL NDC 77934-123-07

Package Label - Principal Display Panel

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic

Uses (s)
Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.

Warnings ----- **For external use only.**
Flammable. Keep away from heat or flame.

Do not use;
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Inactive ingredients Distilled water, Glycerin, Carbomer 940, Trolamine.

MADE IN MEXICO

Distributed by: Supreme foods
2000w 34th St., Chicago Il. 60608

Email: info@mysupremefoods.com



HAND SANITIZER



Moisturizing Gel

75% ETHYL ALCOHOL

WARNING  FLAMMABLE | Keep away from heat, spark, electrical, fire or flame

8.4 FL OZ (250 mL)

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic

Uses (s)
Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.

Warnings ----- **For external use only.**
Flammable. Keep away from heat or flame.

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Inactive ingredients Distilled water, Glycerin, Carbomer 940, Trolamine.

MADE IN MEXICO

Distributed by: Supreme foods
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250 mL NDC 77934-123-08

Package Label - Principal Display Panel

HAND SANITIZER



Moisturizing Gel

75% ETHYL ALCOHOL

WARNING  **FLAMMABLE** | Keep away from heat, spark, electrical, fire or flame

32 FL OZ (1 qt) 946 mL

946 mL NDC 77934-123-09

Package Label - Principal Display Panel

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic

Uses (s)
Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.

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Inactive ingredients Distilled water, Glycerin, Carbomer 940, Trolamine.

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HAND SANITIZER



Moisturizing Gel

75% ETHYL ALCOHOL

WARNING  **FLAMMABLE** | Keep away from heat, spark, electrical, fire or flame

64 FL OZ (1893 mL)

1893 mL NDC 777934-123-10

Package Label - Principal Display Panel

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 75% v/v.....	Antiseptic

Uses (s)
Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.

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Flammable. Keep away from heat or flame.

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- Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients Distilled water, Glycerin, Carbomer 940, Trolamine.

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HAND SANITIZER



Moisturizing Gel

75% ETHYL ALCOHOL

WARNING  **FLAMMABLE** | Keep away from heat, spark, electrical, fire or flame

676.48 FL OZ (20,000 mL)

Drug Facts

Active ingredient Ethyl alcohol 75% v/v.....	Purpose Antiseptic
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Uses (s) Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.
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Directions - Place enough product on hands over 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 15-30 °C (59-86 °F) - Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients Distilled water, Glycerin, Carbomer 940, Trolamine.

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20000 mL NDC 77934-123-13

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77934-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	0.6 mL in 100 mL

TROLAMINE (UNII: 9O3K93S3TK)	0.8 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
WATER (UNII: 059QF0K00R)	18 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77934-123-07	125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2020	
2	NDC:77934-123-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2020	
3	NDC:77934-123-09	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2020	
4	NDC:77934-123-10	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2020	
5	NDC:77934-123-11	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/16/2020	
6	NDC:77934-123-13	20000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	05/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/16/2020	

Labeler - Magaña Muela, Jesús (951577940)

Registrant - Mario Hidalgo (080666336)

Establishment

Name	Address	ID/FEI	Business Operations
Magaña Muela, Jesús		951577940	manufacture(77934-123)

Revised: 5/2020

Magaña Muela, Jesús