

HAND SANITIZER- isopropyl alcohol spray

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

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.

Active Ingredient(s)

Isopropyl Alcohol 75% 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.

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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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Hand Sanitizer



Isopropyl Alcohol Antiseptic 75%

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

TOPICAL SOLUTION
32 FL OZ (1qt) 946 mL

Drug Facts

Active ingredient Isopropyl alcohol 75% v/v.....
Uses (s) 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; - On children less than 2 months of age. - On open skin wounds
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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 Glycerin, hydrogen peroxide, purified water USP.

MADE IN MEXICO
Distributed by: Supreme foods
2000w 34th St., Chicago IL. 60608
Email: info@mysupremefoods.com



7 500326 401145

946 ml NDC: 77934-124-01

Package Label - Principal Display Panel

Hand Sanitizer



Isopropyl Alcohol Antiseptic 75%

WARNING
FLAMMABLE



Keep away from heat, spark,
electrical, fire or flame

TOPICAL SOLUTION

4.2 FL OZ (125 mL)

125 mL NDC: 77934-124-03

Package Label - Principal Display Panel

Drug Facts

Active ingredient

Isopropyl alcohol 75% v/v.....

Uses (s)

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.

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Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.

MADE IN MEXICO

Distributed by: Supreme foods

2000w 34th St., Chicago IL 60608

Email: info@mysupremefoods.com



7 500326 401145

Hand Sanitizer



Isopropyl Alcohol Antiseptic 75%

WARNING
FLAMMABLE



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TOPICAL SOLUTION

128 FL OZ (3785) mL

Drug Facts

Active ingredient

Isopropyl alcohol 75% v/v.....

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Other information

- Store between 15-30 °C (59-86 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.

MADE IN MEXICO

Distributed by: Supreme foods

2000w 34th St., Chicago IL 60608

Email: info@mysupremefoods.com



7 500326 401145

3785 mL NDC: 77934-124-05

Package Label - Principal Display Panel

Hand Sanitizer



Isopropyl Alcohol Antiseptic 75%

WARNING
FLAMMABLE



Keep away from heat, spark,
electrical, fire or flame

TOPICAL SOLUTION

8.4 FL OZ (250) mL

Drug Facts

Active ingredient

Isopropyl alcohol 75% v/v.....

Uses (s)

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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.

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Directions

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Other information

- Store between 15-30 °C (59-86 °F)
- Avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients Glycerin, hydrogen peroxide, purified water USP.

MADE IN MEXICO

Distributed by: Supreme foods

2000w 34th St., Chicago IL 60608

Email: info@mysupremefoods.com



7 500326 401145

250 mL NDC: 77934-124-02

HAND SANITIZER

isopropyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77934-124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77934-124-01	946 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77934-124-03	125 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77934-124-05	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77934-124-02	250 mL in 1 BOTTLE, SPRAY; 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 - Magaña Muela, Jesús (951577940)

Registrant - Mario Hidalgo (080666336)

Establishment			
Name	Address	ID/FEI	Business Operations
Magaña Muela, Jesús		951577940	manufacture(77934-124)

Revised: 5/2020 Magaña Muela, Jesús