

HAND SANITIZER- alcohol gel

Jusseph Jaroslav Cortez Rojas

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.

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) (80%, 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. 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)

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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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

Package Label - Principal Display Panel



Drug Facts	
Active Ingredient(s)	Purpose
Ethyl Alcohol 70%v/v.....	Antiseptic
Use(s)	
Health care personnel hand rub to help reduce bacteria that potentially can cause diseases.	
Warnings	
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Directions	
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Other information	
-Store between 15-30C (59-86F)	
-Avoid freezing and excessive heat above 40C(104F)	
Inactive Ingredients	
Distilled Water, Carbomer 940, Trolamine, Glycerine	

Manufactured by:

Jusseph Jaroslav Cortes Rojas
Calle. 16 #521 Colonia. Valles de San Miguel Guadalupe
Nuevo Leon, Mexico CP 67113
Tel. +(52) 8116121836

Imported by:

Arrgo Logistic Services, LLC
9105 Seguin Dr. Ste. A
Pharr, TX 78577 USA
Tel: (956) 781-1551

LABELER CODE 76809
PRODUCT OF MEXICO

1000 mL NDC: 76809-123-12

Label Principal Display

ETHYL Alcohol Antiseptic
70% Topical Solution

Hand Sanitizer



Antiseptic Hand Rub
Non-sterile Solution

676.28 Fl Oz (20000mL)
Exp 03/2021

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LABELER CODE 76809
PRODUCT OF MEXICO

Label 20000 mL NDC 76809-123-13

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76809-124
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)	1.45 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	17 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:76809-124-12	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76809-124-13	20000 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 - Jusseph Jaroslav Cortez Rojas (951576954)

Registrant - Mario Hidalgo (080666336)

Establishment

Name	Address	ID/FEI	Business Operations
Jusseph Jaroslav Cortes Rojas		951576954	manufacture(76809-124)

Revised: 5/2020

Jusseph Jaroslav Cortez Rojas