

HAND SANITIZER- ethanol alcohol solution
Alquim Especialidades Químicas, S.A. de C.V.

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) (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)

Ethanol Alcohol 72% V/V purpose antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

LEAVES HANDS
Feeling Soft

Alquim®

ADVANCED
HAND
SANITIZER

KILLS MORE THAN 99.99%
OF GERMS WITHOUT WATER

72%
ALCOHOL
BASED
FORMULA

8 oz.
(250 ml.)

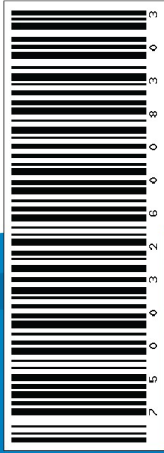
DISTRIBUTED BY COMMERCE UNLIMITED INC.
6553 Star Ct. Laredo Tx 78041
Toll Free 866-386-4096

MADE IN MEXICO

Drug Facts	
Active Ingredient(s): Ethanol Alcohol 72% v/v	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
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Inactive Ingredients Water, Glycerin USP, Carbomer, Triethanolamine, DMDM Hydantion & Perfume	

Water, Glycerin UPS, Carbomer, Triethanolamine, DMDM Hydantion & Perfume

Package Label - Principal Display Panel



Alquim

ADVANCED
**HAND
SANITIZER**

KILLS MORE THAN **99.99%**
OF GERMS WITHOUT WATER

72%
ALCOHOL
BASED
FORMULA

4 oz.
(125 ml.)

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125 mL NDC: 78690-001-01

250 ml NDC: 78690-001-02

3785 ml NDC: 78690-001-03



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HAND SANITIZER

ethanol alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78690-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.24 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.05 mL in 100 mL
DMDM HYDANTOIN (UNII: BYR0546TOW)	0.01 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78690-001-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
2	NDC:78690-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	
3	NDC:78690-001-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2020	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	06/24/2020	

Labeler - Alquim Especialidades Químicas, S.A. de C.V. (812821728)

Registrant - Alquim Especialidades Químicas, S.A. de C.V. (812821728)

Establishment

Name	Address	ID/FEI	Business Operations
Alquim Especialidades Químicas, S.A. de C.V.		812821728	manufacture(78690-001)

Revised: 6/2020

Alquim Especialidades Químicas, S.A. de C.V.