

HAND SANITIZER- alcohol liquid
Asiaticon, 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)

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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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.

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

Water, Glycerin, Aminomethyl Propanol, Carbomer, Proylene Glycol

Package Label - Principal Display Panel

500 mL NDC: 75192-500-01

5.5" X 6.75" (140 X 171 mm)

CMYK + White on Clear BOPP with Gloss Laminata

(Impresi3n cian, magenta, amarillo, negro y tinta blanco. Etiqueta transparente. Laminado brillo)



MEDICALLY MINDED™

5.5"
(140 mm)

Hand
Sanitizer
Gel

ANTIMICROBIAL FORMULA

Drug Facts

Active Ingredients	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin.

Warnings:
Flammable. Keep away from fire or flame.
For external use only.

When using this product do not use in or near the eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using.

Other Information: Store below 110°F (43°C)

Inactive Ingredients: Water (Aqua), Glycerin, Aminomethyl Propanol, Carbomer, Proylene Glycol.

Manufactured by Asiaticon, S.A. de C.V., Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de M3xico, C.P. 14200

Distributed by
SBL Brands, LLC
Las Vegas, NV 89119
MedicallyMinded.us

MADE IN MEXICO

500.358MMC1



16.9 FL OZ (500 mL)

6.75"
(171 mm)



HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75192-500
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
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.4 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.85 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.95 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75192-500-01	500 mL in 1 BOTTLE; 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 - Asiaticon, S.A. de C.V. (951576254)

Registrant - Asiaticon, S.A. de C.V. (951576254)

Establishment

Name	Address	ID/FEI	Business Operations
Asiaticon, S.A. de C.V.		951576254	manufacture(75192-500)