

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.

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 80% 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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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

***CDC RECOMMENDATION:** *RECOMMANDATION DU CDC:
[HTTPS://WWW.CDC.GOV/CORONAVIRUS/2019-NCOV/INFECTION-CONTROL/H-CP-HAND-SANITIZER.HTML](https://www.cdc.gov/coronavirus/2019-ncov/infection-control/hcp-hand-sanitizer.html)

INDICATIONS: ANTISEPTIC CLEANSER. KILLS HARMFUL BACTERIA AND GERMS.

DIRECTIONS: PUT A THUMBNAIL SIZE AMOUNT IN YOUR PALM AND RUB HANDS BRISKLY UNTIL DRY.

ACTIVE INGREDIENT: ALCOHOL 70% **ALSO CONTAINS:** AQUA/WATER/EAU, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE/PERFUM.

NOTE: CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED DURING USE. DO NOT STORE ABOVE 110°F (43°C). MAY DISCOLOUR CERTAIN FABRICS.

CAUTION: FLAMMABLE. KEEP AWAY FROM FIRE AND FLAME. FOR EXTERNAL USE ONLY. KEEP OUT OF EYES. IN CASE OF EYE CONTACT, IMMEDIATELY FLUSH WITH WATER. CALL A PHYSICIAN. IF CONDITION PERSISTS FOR MORE THAN 72 HOURS, CONSULT A PHYSICIAN. KEEP OUT OF REACH OF CHILDREN.

INDICATIONS: NETTOYANT ANTISEPTIQUE TUE LES BACTERIES OU LES GERMS NOCIFES.

MODE D'EMPLOI: DÉPOSEZ-EN UN SOUPÇON DANS LE CREUX DE VOTRE MAIN, ET FROTTEZ-LES ENSEMBLE JUSQU'À CE QU'ELLES SOIENT SÈCHES.

AGENT ACTIF: ALCOOL 70% **CONTIENT AUSSI:** AQUA/WATER/EAU, GLYCÉRINE, CARBOPOL, AMINO MÉTHYLPROPANOL, FRAGRANCE/PARFUM.

NOTE: LES ENFANTS DE MOINS DE 6 ANS DOLVENT UTILISER LE PRODUIT SOUS SUPERVISION. NE PAS ENTREPOSER À UNE TEMPÉRATURE À 43°C NE TACHE PAS, PEUT DÉCOLORER CERTAINS TISSUS.

ATTENTION: INFLAMMABLE. GARDEZ LOIN DU FEU OU DES FLAMMES. POUR USAGE EXTÈME SEULEMENT. GARDEZ LOIN DES YEUX. EN CAS DE CONTACT AVEC LES YEUX, LES ASPERGER IMMÉDIATEMENT À GRANDE EAU. APPELEZ AUSSI UN MÉDECIN. CESSEZ L'UTILISATION EN CAS D'IRRITATION OU D'APPARITION DE ROUGEURS. SI LES SYMPTÔMES PERSISTENT AU-DELÀ DE 72 HEURES, CONSULTEZ UN MÉDECIN.

MADE IN MEXICO IMPORTED & DISTRIBUTED BY
FABRIQUÉ AU MEXIQUE IMPORTÉ ET DISTRIBUÉ PAR

Manufacturing date:
Date de fabrication:

Expiring date:
Date d'expiration:



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V-KLEAN

HAND — — SANITIZER GEL

Clean and fresh



DÉSINFECTANT
POUR
LES MAINS

Effective to a wide spectrum of germs and viruses
Efficace contre un large éventail de germes et de virus

16.9 US/ÉU FL OZ (500ml)



500 mL NDC: 75192-000-01

HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75192-001

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)	0.85 mL in 100 mL		
	AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.5 mL in 100 mL		
	WATER (UNII: 059QF0KO0R)	27.75 mL in 100 mL		
	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.3 mL in 100 mL		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.3 mL in 100 mL		
	FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.2 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75192-001-01	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(75192-001)

Revised: 4/2020

Asiaticon, S.A. de C.V.