HAND SANITIZER LIQUID ANTISEPTIC- alcohol liquid
EPOXEMEX, 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) (70%, 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. Aloe Barbadensis Leaf Extract
c. Fragrance
d. Glycerin
e. Hydrogen peroxide
f. Triethanolamine (TEA)
g. Vitamin E (Tocopheryl Acetate)
h. 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.

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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

Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Hidrogen Peroxide, Triethanolamine (TEA), Vitamin (Tocopheryl Acetate), purified Water USP

Package Label - Principal Display Panel

100mL NDC 79996-350-08

60 mL NDC: 79996-350-01

120 mL NDC 79996-350-02

250 mL NDC 79996-350-03

500 mL NDC 79996-350-04

1000 mL NDC 79996-350-05

4000 mL NDC 79996-350-06

20000 mL NDC 79996-350-07

HAND SANITIZER LIQUID ANTISEPTIC

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79996-350

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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79996-350-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
2	NDC:79996-350-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
3	NDC:79996-350-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
4	NDC:79996-350-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
5	NDC:79996-350-05	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
6	NDC:79996-350-06	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
7	NDC:79996-350-07	20000 mL in 1 TANK; Type 0: Not a Combination Product	12/30/2021	
8	NDC:79996-350-08	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/30/2021	

Labeler - EPOXEMEX, S.A. DE C.V. (814573127)

Registrant - AY CONSULTING SERVICES, LLC (078311971)

Establishment

Name	Address	ID/FEI	Business Operations
EPOXEMEX, S.A. DE C.V.		814573127	manufacture(79996-350)

Revised: 5/2023

EPOXEMEX, S.A. DE C.V.