### 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.

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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**

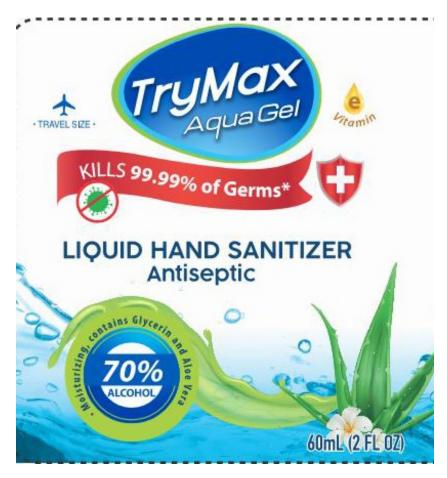
Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Hidrogen Peroxide, Triethanolamine (TEA), Vitamin (Tocopheryl Acetate), purified Water USP

### Package Label - Principal Display Panel



### HAND SANITIZER ANTISEPTIC LIQUID





120 mL NDC 79996-350-02



250 mL NDC 79996-350-03



500 mL NDC 79996-350-04



# LIQUID HAND SANITIZER Antiseptic 500ml (16.9 FL 0Z)



# LIQUID HAND SANITIZER Antiseptic 1 (33.84 FL 07)



# LIQUID HAND SANITIZER Antiseptic 4L (135.2 FL 0Z)





### 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	<b>Basis of Strength</b>	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: 903K93S3TK)			
.ALPHATOCOPHEROL 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	<b>Business Operations</b>		
EPOXEMEX, S.A. DE C.V.		814573127	manufacture(79996-350)		

Revised: 5/2023 EPOXEMEX, S.A. DE C.V.