

**HAND SANITIZER- alcohol aerosol, foam
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.

Aquagel Plus

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. Lactic Acid
- f. PEG 400
- g. TEA
- 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

- On 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 15-35C (59-95F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Aloe barbadensis leaf extract, fragrance, glycerin, lactic acid, PEG 400, TEA, purified water USP

Package Label - Principal Display Panel

50 mL NDC: 79996-600-03



PLUS+
Antibacterial Foam
Hand Sanitizer



Kills 99.99% of Germs*

50 mL (1.7 FL OZ)



**Moisturizing
Aloe vera Extract**

ANTISEPTIC HAND SANITIZER FOR EXTERNAL USE
when access to soap and water is not available

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses

■ Hand sanitizer to help decrease 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 and flame

Do not use

- On 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, rise eyes thoroughly with water.

Stop use and ask a doctor if irritation, sensitization or allergic reaction 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 - 35°C, (59-95°F) ■ Avoid freezing and excessive heat above 40°C (104°F)

inactive ingredients: ■ Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Lactic Acid, PEG 400, TEA, Water

Questions? Call 01-800-714-9531 Email: ventas@epoxemex.com

Manufactured by:
Epoxemex S.A de C.V.
Benito Juarez No. 735 Col. Santa Maria Aztahuacan
Alcaldia iztapalapa, Mexico City, C.P. 09500
Mexico

MADE IN MEXICO
Imported/Distributed by:



* Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds.

160 mL NDC: 79996-600-02



PLUS+
Antibacterial Foam
Hand Sanitizer



Kills **99.99%** of Germs*

160 mL (5.4 FL OZ)



Moisturizing
Aloe vera Extract

ANTISEPTIC HAND SANITIZER FOR EXTERNAL USE
when access to soap and water is not available

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses

Hand sanitizer to help decrease 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 and flame

Do not use

- On children less than 2 months of age
- On open skin wounds

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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 - 35°C, (59-95°F) Avoid freezing and excessive heat above 40°C (104°F)

inactive ingredients: Aloe Barbadosis Leaf Extract, Fragrance, Glycerin, Lactic Acid, PEG 400, TEA, Water

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Mexico

MADE IN MEXICO

Imported/Distributed by:



*Effective at eliminating 99.9% of many common harmful germs and bacteria in as little as 15 seconds.

230 mL NDC: 79996-600-01



PLUS+
Antibacterial Foam
Hand Sanitizer



Kills **99.99% of Germs***

230 mL (7.7 FL OZ)



Moisturizing
Aloe vera Extract

ANTISEPTIC HAND SANITIZER FOR EXTERNAL USE
when access to soap and water is not available

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses

Hand sanitizer to help decrease 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 and flame

Do not use

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HAND SANITIZER

alcohol aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79996-600
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
TROLAMINE (UNII: 9O3K93S3TK)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
LACTIC ACID (UNII: 33X04XA5AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79996-600-01	230 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79996-600-02	160 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79996-600-03	50 mL in 1 BOTTLE, PUMP; 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 - 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(79996-600)

Revised: 6/2022

EPOXEMEX, S.A. DE C.V.