

AQUAGEL ADVANCED FORMULA- hand sanitizer gel 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. Carbomer
- d. Fragrance
- e. Glycerin
- f. Triethanolamine
- g. 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 15-35C (59-95F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Aloe Barbadensis Leaf Extract, Carbomer, Fragrance, Glycerin, Triethanolamine, Water

Package Label - Principal Display Panel

100 mL NDC: 79996-300-22



KILLS 99.99% of Germs*



HAND SANITIZER ANTISEPTIC GEL



Net wt. 100 mL (3.38 FL OZ)

60 mL NDC: 79996-300-15



120 ml NDC: 79996-300-16



HAND SANITIZER ANTISEPTIC GEL





HAND SANITIZER ANTISEPTIC GEL





HAND SANITIZER ANTISEPTIC GEL



1 L NDC: 79996-300-19



HAND SANITIZER ANTISEPTIC GEL



1L (33.81 FL OZ)

4000 mL NDC: 79996-300-20



HAND SANITIZER ANTISEPTIC GEL



4L (135.2 FL OZ)

20L NDC: 79996-300-21



HAND SANITIZER ANTISEPTIC GEL



946.3 L NDC: 79996-300-14



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

946.3 L (250 Gal)

189.92 L NDC: 79996-300-13



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

189.2 L (50 Gal)

113.5 L NDC: 79996-300-12



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

113.5 L (30Gal)

20 L NDC: 79996-300-11



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Aloe Vera extract

20 L (676.28 FL OZ)

500 mL NDC: 79996-300-10



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

500 mL (16.90 FL OZ)

300 mL NDC: 79996-300-09



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

300 mL (10.14 FL OZ)

250 mL NDC: 79996-300-08



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

250 mL (8.45 FL OZ)

120 mL NDC: 79996-300-07



Hand sanitizer Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

120 mL (4.057 FL OZ)

100 mL NDC: 79996-300-06



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

100 mL (3.38 FL OZ)

60 mL NDC: 79996-300-05



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral Fragrance



Aloe Vera extract

60 mL (2.028 FL OZ)

4000 mL NDC: 79996-300-04



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Aloe Vera extract

4L (135.25 FL OZ)

1000 mL NDC: 79996-300-03



Hand sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



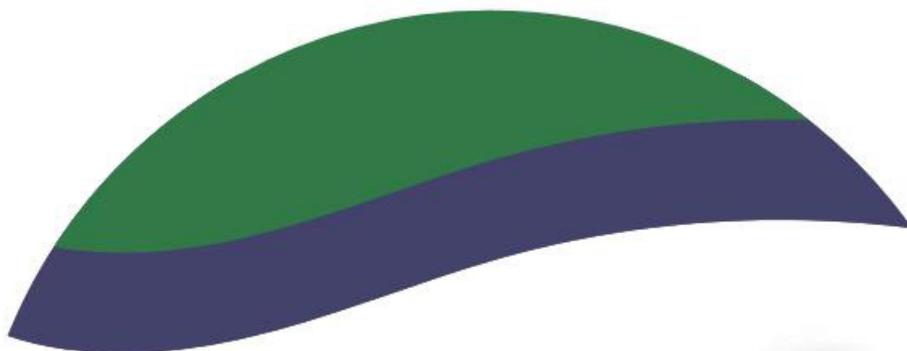
Floral Fragrance



Aloe Vera extract

1 L (33.84 FL OZ)

107 mL NDC: 79996-300-02





Hand Sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



Floral fragrance



ALOE VERA EXTRACT

170 mL (5.7 FL OZ)

52 mL NDC: 79996-300-01





Aqua Gel™

ADVANCED FORMULA

Hand Sanitizer

Antibacterial

Moisturizing - Antiseptic Gel

Kills 99.9% of germs*



ALOE VERA EXTRACT



Floral Fragrance

52mL (1.7 FL OZ)

AQUAGEL ADVANCED FORMULA

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79996-300
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)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79996-300-04	4000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	12/31/2021
2	NDC:79996-300-01	52 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
3	NDC:79996-300-02	170 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
4	NDC:79996-300-03	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
5	NDC:79996-300-05	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79996-300-06	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
7	NDC:79996-300-07	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
8	NDC:79996-300-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
9	NDC:79996-300-09	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
10	NDC:79996-300-10	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
11	NDC:79996-300-11	20000 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	12/31/2021
12	NDC:79996-300-12	113500 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	12/31/2021

13	NDC:79996-300-13	189920 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	12/31/2021
14	NDC:79996-300-14	946300 mL in 1 TANK; Type 0: Not a Combination Product	03/30/2020	12/31/2021
15	NDC:79996-300-15	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
16	NDC:79996-300-16	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
17	NDC:79996-300-17	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
18	NDC:79996-300-18	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
19	NDC:79996-300-19	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
20	NDC:79996-300-20	4000 mL in 1 TANK; Type 0: Not a Combination Product	12/30/2021	
21	NDC:79996-300-21	20000 mL in 1 TANK; Type 0: Not a Combination Product	12/30/2021	
22	NDC:79996-300-22	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	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(79996-300)

Revised: 5/2023

EPOXEMEX, S.A DE C.V.