

HAND SANITIZER- ethyl alcohol gel

CAPNA Fabrication

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)

Ethyl 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

- 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.

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Purified Water, Acrylates Copolymer, Glycerin, Aminomethylpropanol, Hydrogen Peroxide

Package Label - Principal Display Panel

The label image provided below,



Hand Sanitizing Gel By CAPNA Sanitizer		Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution 12.6 oz (375ml)
Conforms to WHO, FDA, CDC and EN12791 guidance for COVID-19		
Drug Facts		
Active ingredient Ethyl Alcohol 80% v/v.....		Purpose Antiseptic
Uses Use sanitizer on hands or surfaces as a disinfecting agent to kill viruses and bacteria		
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 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. 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 15-30C (59 - 85F) ■ Avoid freezing and excessive heat above 40C (104F)		
Inactive ingredients: aminomethylpropanol, acrylates copolymer, glycerin, hydrogen peroxide, purified water		

NDC 76972-001-06 EXP. 05/2023 BATCH #2101

Manufactured and packaged in a federally licensed facility in the USA.
Distributed by CAPNA Sanitizer, Sylmar, CA
www.capnasanitizer.com (661) 263-4329

pertains to the following packaging sizes and NDC codes:

2 Oz / 59 mL 77434-001-01

4 Oz / 118 mL 77434-001-02

6.4 Oz / 189 mL 77434-001-03

8 Oz / 236 mL 77434-001-04

11.8 Oz / 349 mL 77434-001-05

12.6 Oz / 375 mL 77434-001-06

16 Oz / 473 mL 77434-001-07

1 Gal / 3785 mL 77434-001-11

Package Label - Principal Display Panel

The label image provided below,



Hand Sanitizing Gel By CAPNA Sanitizer

Conforms to WHO, FDA, CDC and
EN12791 guidance for COVID-19

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution
12.6 oz (375ml)

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 80% v/v.....	Antiseptic

Uses

Use sanitizer on hands or surfaces as a disinfecting agent to kill viruses and bacteria

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

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.

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 15-30C (59 - 85F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients: aminomethylpropanol, acrylates copolymer, glycerin, hydrogen peroxide, purified water

NDC 76972-001-06

EXP. 05/2023

BATCH #2101

Manufactured and packaged in a federally licensed facility in the USA.

Distributed by CAPNA Sanitizer, Sylmar, CA

www.capnasanitizer.com (661) 263-4329

pertains to the following packaging sizes and NDC codes:

2 Oz / 59 mL 77434-002-01

4 Oz / 118 mL 77434-002-02

6.4 Oz / 189 mL 77434-002-03

8 Oz / 236 mL 77434-002-04

11.8 Oz / 349 mL 77434-002-05

12.6 Oz / 375 mL 77434-002-06

16 Oz / 473 mL 77434-002-07

1 Gal / 3785 mL 77434-002-11

HAND SANITIZER

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77434-002	
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	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			0.2 mL in 100 mL	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)			7 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)			1.42 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)			21.255 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77434-002-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77434-002-11	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77434-002-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77434-002-03	189 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77434-002-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77434-002-05	349 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77434-002-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:77434-002-06	375 mL in 1 BOTTLE, PLASTIC; 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	

HAND SANITIZER				
ethyl alcohol gel				
Product Information				

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:77434-001		
Route of Administration		TOPICAL				
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	80 mL in 100 mL		
Inactive Ingredients						
Ingredient Name				Strength		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				0.2 mL in 100 mL		
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)				7 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)				1.42 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				11.255 mL in 100 mL		
Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:77434-001-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
2	NDC:77434-001-11	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020			
3	NDC:77434-001-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
4	NDC:77434-001-03	189 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
5	NDC:77434-001-04	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
6	NDC:77434-001-05	349 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
7	NDC:77434-001-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
8	NDC:77434-001-06	375 mL in 1 BOTTLE, PLASTIC; 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 - CAPNA Fabrication (019040504)

Registrant - CAPNA Fabrication (019040504)

Establishment

Name	Address	ID/FEI	Business Operations
CAPNA Fabrication		019040504	manufacture(77434-001, 77434-002)

Revised: 9/2020

CAPNA Fabrication