

CITADEL PPE HAND SANITIZER- alcohol gel

Citadel PPE LLC

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)

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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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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

3.785 L NDC: 77494-966-01



Silver Material



3.75 L NDC: 77494-966-02



Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Use	
■ hand sanitizer to help reduce bacteria on the skin	
Warnings	
Flammable. Keep away from fire or flame.	
For external use only	
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash appears and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ put enough product in your palm to cover all surfaces of both hands and rub hands together briskly until dry ■ children under 6 years of age should be supervised when using this product	
Other information ■ store at 20-30°C (68-86°F)	
Inactive Ingredients: Aloe Vera Leaf Juice, Carbomer and/or Acrylates Copolymer, Essential Oils, Glycerin, Isopropyl Alcohol, Panthenol, Propylene Glycol, Tocopheryl Acetate (Vitamin E), Triethanolamine, Water (Aqua).	

DISTRIBUTED BY HAPPY HOME
 1903 MCMILLAN AVE.
 SUITE 2 DALLAS, TX 75206
 HAPPYHOMEUSA.COM
 (214) 932 9133



1 US Gallon / 3.78 L

CITADEL PPE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77494-966
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2.65 kg in 3.78 kg

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	0.0004 kg in 3.78 kg
WATER (UNII: 059QF0KO0R)	0.849 kg in 3.78 kg
ISOPROPYL ALCOHOL (UNII: ND2M416302)	0.038 kg in 3.78 kg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0001 kg in 3.78 kg
GLYCERIN (UNII: PDC6A3C0OX)	0.019 kg in 3.78 kg
CARBOMER 940 (UNII: 4Q93RCW27E)	0.009 kg in 3.78 kg
PEPPERMINT OIL (UNII: AV092KU4JH)	0.002 kg in 3.78 kg
PANTHENOL (UNII: WV9CM0O67Z)	0.002 kg in 3.78 kg
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.019 kg in 3.78 kg
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.004 kg in 3.78 kg
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	0.004 kg in 3.78 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77494-966-01	3.78 kg in 1 JUG; Type 0: Not a Combination Product	04/20/2020	
2	NDC:77494-966-02	3.78 kg in 1 JUG; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/20/2020	

Labeler - Citadel PPE LLC (117518098)

Establishment

Name	Address	ID/FEI	Business Operations
Citadel PPE LLC		117518098	manufacture(77494-966)

Revised: 6/2020

Citadel PPE LLC