

HAND SANITIZER- ethanol alcohol gel

2ProtékU,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 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

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

000 mL NDC: 00000-000-00



Gel

Hand Sanitizer

Non-Sterile Solution

Alcohol Antiseptic 70%
Topical Solution

473 ml

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic
Use: •Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are unavailable	
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 •in eyes	
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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under age 6 when using this product to avoid swallowing.	
Other information • Store between 59-86F (15-30C) • Avoid freezing and excessive heat above 104F (40C)	
Inactive ingredients acrylates copolymer, alpha-tocopherol acetate, denatonium benzoate, glycerin, isopropyl myristate, propylene glycol, tert-butyl alcohol, triisopropanolamine	

Distributed by:
AMA Systems
8160 Lark Brown Rd.
Elkridge, MD 21075

2ProtekU.com





Gel

Hand Sanitizer

Non-Sterile Solution

Alcohol Antiseptic 70%
Topical Solution

1 Gallon (3,785 ml)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic
Use: •Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are unavailable	
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 •in eyes	
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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under age 6 when using this product to avoid swallowing.	
Other information • Store between 59-86F (15-30C) • Avoid freezing and excessive heat above 104F (40C)	
Inactive ingredients acrylates copolymer, alpha-tocopherol acetate, denatonium benzoate, glycerin, isopropyl myristate, propylene glycol, tert-butyl alcohol, triisopropanolamine	

Distributed by:
AMA Systems
8160 Lark Brown Rd.
Elkridge, MD 21075

2ProtekU.com





Gel

Hand Sanitizer

Non-Sterile Solution

Alcohol Antiseptic 70%
Topical Solution

8 fl oz (236 ml)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic
Use: •Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are unavailable	
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 •in eyes	
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.	
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under age 6 when using this product to avoid swallowing.	
Other information • Store between 59-86F (15-30C) • Avoid freezing and excessive heat above 104F (40C)	
Inactive ingredients acrylates copolymer, alpha-tocopherol acetate, denatonium benzoate, glycerin, isopropyl myristate, propylene glycol, tert-butyl alcohol, triisopropanolamine	

Distributed by:
AMA Systems
8160 Lark Brown Rd.
Elkridge, MD 21075

2ProtekU.com



Distributed by:
 AMA Systems
 8160 Lark Brown Rd.
 Elkridge, MD 21075



HAND SANITIZER

70% Alcohol
 GEL Antiseptic

2 fl oz (59 ml)

Batch#: 2Pro-0000010 expires: Jun-2022

Drug Facts	
Active ingredient(s) Alcohol 70% v/v	Purpose Antiseptic
Use: •Hand sanitizer to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are unavailable	
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 •in eyes	
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.	
Directions •Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 when using this product to avoid swallowing.	
Other information • Store between 59-86F (15-30C) • Avoid freezing and excessive heat above 104F (40C)	
Inactive ingredients acrylates copolymer, alpha-tocopherol acetate, denatonium benzoate, glycerin, isopropyl myristate, propylene glycol, tert-butyl alcohol, triisopropanolamine	

HAND SANITIZER

ethanol alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77806-678
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 70 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
MCPA TRIISOPROPANOLAMINE (UNII: 135JRI07JR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77806-678-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

2	NDC:77806-678-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77806-678-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77806-678-04	59 mL in 1 BOTTLE; 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 - 2ProtekU,LLC (131401095)

Establishment

Name	Address	ID/FEI	Business Operations
2ProtekU, LLC		131401095	manufacture(77806-678)

Revised: 6/2020

2ProtekU,LLC