

PPE GLOBAL HEALTH HAND SANITIZER- alcohol solution
PPE GLOBAL HEALTH

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.

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

2 FL OZ(59 mL) NDC: 79576-001-01

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s] 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	
<ul style="list-style-type: none"> • in 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	
<ul style="list-style-type: none"> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	
Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).	

PPEGlobalHealth®

Hand Sanitizer
Non-sterile Solution



Alcohol Antiseptic 80%
Topical Solution

2 FL OZ (59 mL)

Distributed by: PPE Global Health
1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com Made in Canada LOT:



Package Label - Principal Display Panel

16 FL OZ(473 mL) NDC: 79576-001-02

PPEGlobalHealth[®]

Hand Sanitizer

Non-sterile Solution



Alcohol Antiseptic 80%
Topical Solution

16 FL OZ (473 mL)

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s] 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

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Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).

Distributed by: PPE Global Health
1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com
Made in Canada
LOT:



Package Label - Principal Display Panel

32 FL OZ(946 mL) NDC: 79576-001-03

PPEGlobalHealth[®]

Hand Sanitizer

Non-sterile Solution



Alcohol Antiseptic 80%
Topical Solution

32 FL OZ (946 mL)

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s] 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

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Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).

Distributed by: PPE Global Health
1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com
Made in Canada
LOT:



Package Label - Principal Display Panel

128 FL OZ(3785 mL) NDC: 79576-001-04

PPEGlobalHealth[®]

Hand Sanitizer

Non-sterile Solution



Alcohol Antiseptic 80%
Topical Solution

128 FL OZ (3785 mL)

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

Use[s] 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

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Questions? 1-855-368-1585 (M-F 8:30am-4:30pm EST).

Distributed by: PPE Global Health
1022 E Lancaster Ave, Bryn Mawr, Pa 19010 USA
PPEGlobalHealth.com
Made in Canada
LOT:



PPE GLOBAL HEALTH HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79576-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 1000 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 1000 mL
WATER (UNII: 059QF0K00R)	18.425 L in 1000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79576-001-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
2	NDC:79576-001-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
3	NDC:79576-001-03	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
4	NDC:79576-001-04	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/13/2020	

Labeler - PPE GLOBAL HEALTH (117580016)

Registrant - DVINE LABORATORIES INC (203454749)

Establishment

Name	Address	ID/FEI	Business Operations
DVINE LABORATORIES INC		203454749	manufacture(79576-001)