

HAND SANITIZER - ETOH- alcohol liquid

Phillips 66 Company

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.

P66 Hand Sanitizer EtOH

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.

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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

- 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

KDW-20095001 1 gallon		Hand Sanitizer - ETOH	PHILLIPS 66
Drug Facts		Active Ingredient(s): Alcohol 80% v/v	Purpose: Antiseptic
Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease.			
Warnings: For external use only. Flammable. Keep away from heat or flame. Do not use in children less than two (2) months of age; on open skin wounds When using this product keep out of eyes, ears, and mouth. In case of contact, rinse 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 six (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 ingredient(s): glycerin, hydrogen peroxide, purified water USP			
MANUFACTURED BY: Phillips 66 Company, P.O. Box 421959, Houston, TX 77242 www.phillips66.com			

KDW-20095002 1 gallon		Hand Sanitizer - ETOH	PHILLIPS 66
Drug Facts		Active Ingredient(s): Alcohol 80% v/v	Purpose: Antiseptic
Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease.			
Warnings: For external use only. Flammable. Keep away from heat or flame. Do not use in children less than two (2) months of age; on open skin wounds When using this product keep out of eyes, ears, and mouth. In case of contact, rinse 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 six (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 ingredient(s): glycerin, hydrogen peroxide, purified water USP			
MANUFACTURED BY: Phillips 66 Company, P.O. Box 421959, Houston, TX 77242 www.phillips66.com			

KDW-20095003 1 gallon		Hand Sanitizer - ETOH	PHILLIPS 66
Drug Facts		Active Ingredient(s): Alcohol 80% v/v	Purpose: Antiseptic
Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease.			
Warnings: For external use only. Flammable. Keep away from heat or flame. Do not use in children less than two (2) months of age; on open skin wounds When using this product keep out of eyes, ears, and mouth. In case of contact, rinse 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 six (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 ingredient(s): glycerin, hydrogen peroxide, purified water USP			
MANUFACTURED BY: Phillips 66 Company, P.O. Box 421959, Houston, TX 77242 www.phillips66.com			

KDW-20095004 1 gallon		Hand Sanitizer - ETOH	PHILLIPS 66
Drug Facts		Active Ingredient(s): Alcohol 80% v/v	Purpose: Antiseptic
Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease.			
Warnings: For external use only. Flammable. Keep away from heat or flame. Do not use in children less than two (2) months of age; on open skin wounds When using this product keep out of eyes, ears, and mouth. In case of contact, rinse 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 six (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 ingredient(s): glycerin, hydrogen peroxide, purified water USP			
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HAND SANITIZER - ETOH

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74635-001
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	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74635-001-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
2	NDC:74635-001-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
3	NDC:74635-001-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
4	NDC:74635-001-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
5	NDC:74635-001-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
6	NDC:74635-001-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
7	NDC:74635-001-03	88.7 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
8	NDC:74635-001-91	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
9	NDC:74635-001-92	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
10	NDC:74635-001-93	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2020	
11	NDC:74635-001-07	207 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/10/2020	
12	NDC:74635-001-64	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/03/2020	

Labeler - Phillips 66 Company (078378508)

Establishment

Name	Address	ID/FEI	Business Operations
Phillips 66 Company		078378508	manufacture(74635-001) , repack(74635-001)

