

HAND SANITIZER- alcohol liquid

Washington State University

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.

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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

237 mL NDC: 74363-001-01

**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-Sterile Solution**

8 ounces



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	Antiseptic	
Use(s):		
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.		
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Do Not Use:	In children under 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	Store between 15-30C (59-86F)	Avoid freezing or heat > 40C (104F)

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

354 mL NDC: 74363-001-02

**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-Sterile Solution**

12 ounces



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	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 under 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 or heat > 40C (104F)

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

473 mL NDC: 74363-001-03

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

16 ounces



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	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 under 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 or heat > 40C (104F)	
Inactive Ingredients: glycerin, hydrogen peroxide, purified water		

946 mL NDC: 74363-001-04

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

32 ounces



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	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 under 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 or heat > 40C (104F)	
Inactive Ingredients: glycerin, hydrogen peroxide, purified water		

100 mL NDC: 74363-001-05

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

100 mL



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	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 under 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.		
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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 or heat > 40C (104F)	
Inactive Ingredients: glycerin, hydrogen peroxide, purified water		

500 mL NDC: 74363-001-06

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

500 mL



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	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 under 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 or heat >40C (104F)
Inactive Ingredients: glycerin, hydrogen peroxide, purified water		

750 mL NDC: 74363-001-07

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

750 mL



Drug Facts		
Active Ingredients	Purpose	
Alcohol 79%	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 under 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 or heat >40C (104F)
Inactive Ingredients: glycerin, hydrogen peroxide, purified water		

1000 mL NDC: 74363-001-08

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution

1000 mL



Drug Facts

Active Ingredients		Purpose
Alcohol 79%		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:		On open skin wounds
In children under 2 months of age		
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 or heat >40C (104F)	
Inactive ingredients: glycerin, hydrogen peroxide, purified water		

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74363-001
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74363-001-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:74363-001-02	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
3	NDC:74363-001-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
4	NDC:74363-001-04	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
5	NDC:74363-001-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
6	NDC:74363-001-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
7	NDC:74363-001-07	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
8	NDC:74363-001-08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Washington State University (041485301)

Establishment

Name	Address	ID/FEI	Business Operations
Washington State University		041485301	manufacture(74363-001)

Revised: 3/2020

Washington State University