COUGAR CLEAN 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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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: 74363-002-01



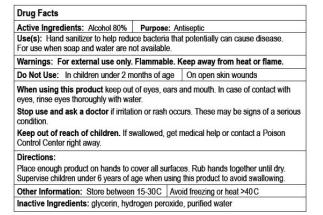


topical non-sterile solution alcohol antiseptic 80%

8 oz. NDC: 74363-002-01



355 mL NDC: 74363-002-02



Please return containers when empty. Contact sampsonj@wsu.edu EMPLOYEE USE ONLY. Not for resale.





topical non-sterile solution alcohol antiseptic 80%

12 oz. NDC: 74363-002-02



Drug Facts

Active Ingredients: Alcohol 80% Purpose: Antiseptic

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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 Avoid freezing or heat >40 C Inactive Ingredients: glycerin, hydrogen peroxide, purified water

Please return containers when empty. Contact sampsonj@wsu.edu EMPLOYEE USE ONLY. Not for resale. 473 mL NDC: 74363-002-03





topical non-sterile solution alcohol antiseptic 80%

16 oz. NDC: 74363-002-03



946 mL NDC: 74363-002-04





topical non-sterile solution alcohol antiseptic 80%

32 oz. NDC: 74363-002-04







100 mL NDC: 74363-002-05





topical non-sterile solution alcohol antiseptic 80%

100mL NDC: 74363-002-05



Drug Facts

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Other Information: Store between 15-30C | Avoid freezing or heat >40 C Inactive Ingredients: glycerin, hydrogen peroxide, purified water

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Drug Facts

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Drug Facts

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Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition

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Directions:

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Other Information: Store between 15-30C Avoid freezing or heat >40 C Inactive Ingredients: glycerin, hydrogen peroxide, purified water

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EMPLOYEE USE ONLY. Not for resale.

500 mL NDC: 74363-002-06





topical non-sterile solution alcohol antiseptic 80%

500mL NDC: 74363-002-06



750 mL NDC: 74363-002-07





topical non-sterile solution alcohol antiseptic 80%

750mL NDC: 74363-002-07



1 L NDC: 74363-002-08





topical non-sterile solution alcohol antiseptic 80%

NDC: 74363-002-08



Drug Facts

Active Ingredients: Alcohol 80% Purpose: Antiseptic

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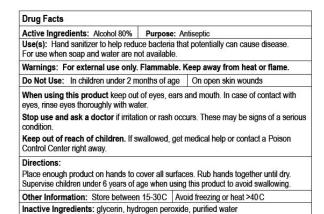


topical non-sterile solution alcohol antiseptic 80%

1 Gallon NDC: 74363-002-09



7.5 L NDC: 74363-002-09



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topical non-sterile solution alcohol antiseptic 80%

7.5 Liter NDC: 74363-002-10



Drug Facts

Active Ingredients: Alcohol 80% Purpose: Antiseptic

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Other Information: Store between 15-30C Avoid freezing or heat >40C Inactive Ingredients: glycerin, hydrogen peroxide, purified water

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COUGAR CLEAN HAND SANITIZER

alcohol liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:74363-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	8		
ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Pá	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:74363-002-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
2	NDC:74363-002-02	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
3	NDC:74363-002-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
4	NDC:74363-002-04	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
5	NDC:74363-002-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
6	NDC:74363-002- 06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
7	NDC:74363-002-07	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
8	NDC:74363-002- 08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
9	NDC:74363-002- 09	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			
10	NDC:74363-002-10	7500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/14/2020			

Labeler - Washington State University (041485301)

Establishment					
Name	Address	ID/FEI	Business Operations		
Washington State University		041485301	manufacture(74363-002)		

Revised: 5/2020 Washington State University