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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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

237 mL NDC: 74363-001-01

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



354 mL NDC: 74363-001-02

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



Active Ingredients		Purpose	
Alcohol 79%	Antisepti		
Use(s):		0.000	
Hand sanifizer to he when soap and wab	lp reduce bacteria that potentially (er are not available.	can cause disease. Foruse	
Warnings:			
Forexternaluae o	nly. Flammable . Keep away from	nheatorflame	
Do Not Use: In	children under 2 months of age	On open skin wounds	
with eyes, rinse eye	od uct keep out of eyes, ears and s thoroughly with water.		
serious cond i ion	a doctorifinitation or rash occurs.		
Control Centerright	of c hildrøn. If swallowed, get med away.	lical help or contact a Poison	
Directions	985 65 6345 IN 95	INCIDE AREA NO. ANDA	
	ict on hands to cover all suifaces. Inder б years of age when usingth		
s upervise children u swallowing.			

Drug Facta				
Active Ingredients	ctive Ingredienta Purpos			
Alcohol 79%		Antiseptio		
Use(s):	ALL ALL PROPERTY AND A PARTY	201 0.0		
Hand sanitizer to ho when soap and wa	spreduce bacteriathat potentially (er are not available.	can cause disease. Foruse		
Warnings:				
Forexternaluae o	nly. Flammable. Keep away from	nheatorflame		
Do Not Use: Ir	children under 2 months of age	On open skin wounds		
	roduct keep out of eyes, ears and is thoroughly with water.	mouth. In case of contact		
Stop use and ask serious condition	a doctorifinitation or rash occurs.	These may be signs of a		
Keepout of reach	of children. If swallowed, get med	lical help or contact a Poison		
Control Centerrigh	taway.			
Directions				
Supervise children	uction hands to cover all surfaces. I under 6 years of age when using th			
swallowing.				
Other Information	Store between 15-30C (59- 86F)	Avoid freezing or heat>40C (104F)		

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



946 mL NDC: 74363-001-04

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



100 mL NDC: 74363-001-05

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



Active Ingredients	C2	Purpose		
Alcohol 79%		Antiseptio		
Use(s):		0.0000		
Hand sanitizer to he when soap and wat	ap reduce bacteria that potentially er are not available.	can cause disease. Foruse		
Warnings:				
Forexternaluae o	nly. Flammable. Keep away from	nheatorflame		
Do Not Use: In	children under 2 months of age	On open skin wounds		
with eyes, rinse eye	roduct keep out of eyes, ears and 2s thoroughly with water.			
Stopuse and ask: serious condition	a doctorifinitation or rash occurs	. These may be signs of a		
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	uct on hands to cover all surfaces. under 6 years of age when using t			
Other Information	Store between 15-30C (59- 86F)	Avoid freezing or heat>40C (104F)		

Inactive Ingredients: glycerin, hydrogen percoide, purified water

Active Ingredier	nta 🔤	Purpose		
Alcohol 79%		Antiseptio		
Use(s):	annen ta ta ²⁰ annen enter anne	65. 47		
	help reduce bacteria that potentially (vater are not available.	an cause disease. Foruse		
Warnings:				
Forexternaluae	only. Flammable. Keep away from	nheatorflame		
Do Not Use:	In children under 2 months of age	On open skin wounds		
with eyes, rinse (i product keep out of eyes, ears and eyes thoroughly with water.			
Stop use and as serious condition	aka doctorifimitation orrash occurs.	These may be signs of a		
	ch of children. If swallowed, get med	lical help or contact a Poison		
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Keepout of rea Control Centerni <i>Directions</i>	,,,			
Control Centerri Directions Place enough pr	,,,			

Drug Facta				
Active Ingredients		Purpose		
Alcohol 79%		Antisepti		
Use(s):		2020-2020 (A.M.)		
Hand sanitizer to hell when soap and wate	preduce bacteriathat potentially (rrare not available.	an cause disease. Foruse		
Warnings:	LUNCTION OF STREET, ST	An 10280-400, Re-2003-0		
Forexternaluaeor	ily. Flammable. Keep away from	nheatorflame		
Do Not Use: In	children under 2 months of age	On open skin wounds		
with eyes, rinse eye:	od uct keep out of eyes, ears and s thoroughly with water.			
Stop use and aska serious condition	doctor if initiation or rash occurs.	These may be signs of a		
Keepout of reach o Control Centerright	of c hildrøn. If swallowed, get med away.	lical help or contact a Poison		
Directions	THE TREAT PROPERTY OF	organism source of which		
	ct on hands to cover all surfaces. I			
Supervise children u swallowing.	nder 6 years of age when using th	iis productto avoid		
Other Information	Store between 15-30C (59- 86F)	Avoid freezing or heat>40C (104F)		
Inactive Ingredient	a: glycerin, hydrogen peroxide, pu	urified water		

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



Drug Facta		
Active Ingredients		Purpose
Alcohol 79%		Antiseptic
Use(s):		
Hand sanitizer to he when soap and wate	lp reduce bacteria that potentially er are not available.	can cause disease. Foruse
Warninga:	60 X00 X X00	23 23 34
Forexternaluse or	ily. Flammable, Keep away from	m heat or flame
Do Not Use: In	children under 2 months of age	On open skin wounds
with eyes, rinse eye:	od uct keep out of eyes, ears and s thoroughly with water. doctor if infitation or rash occurs	
serious condition		. The child is chight of a
Keepout of reach o Control Centerright	of children. If swallowed, get me away.	dical helpor contact a Poison
Directions	alla an exerce e	1000 000 000 000 00000
	ct on hands to cover all surfaces. Inder 6 years of age when using t	
Other Information	Store between 15-30C (59-	Avoid freezing or heats40C (104E)

86F) heat>40C (104F) Inactive Ingredients: glycerin, hydrogen peroxide, purified water

Dave Dave

750 mL NDC: 74363-001-07

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



1000 mL NDC: 74363-001-08

Active Ingredients	0	Purpose		
Alcohol 79%		Antiseptio		
Use(s):		C.S. 4. (6. 7 a)		
Hand sanitizer to he when soap and wate	preduce bacteriathat potentially : rrare not available.	can cause disease. Foruse		
Warnings:	Ge (64) 1441 552 574	318 #33554eV		
Forexternal use or	ily. Flammable, Keep away from	nheatorflame		
Do Not Use: In	children under 2 months of age	On open skin wounds		
with eyes, rinse eye:	od uct keep out of eyes, ears and s thoroughly with water.			
Stopuse and aska serious condition	doctorifimitation or rash occurs	. These may be signs of a		
Keepout of reach of Control Centerright	of children. If swallowed, get med away.	ilical helpor contact a Poison		
Directions	19 ¹⁵ 19 1919 19 19 19			
	ct on hands to cover all surfaces. Inder 6 years of age when using t			
Other Information	Store between 15-30C (59-	Avoid freezing or heat>40C (104F)		

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-Sterile Solution



Drug Facta		
Active Ingredients		Purpose
Alcohol 79%		Antiseptic
Use(s):		
Hand sanifizer to hel when soap and wate	lp reduce bacteriathat potentially er are not available.	can cause disease. Foruse
Warnings:		
Forexternaluse or	ily. Flammable. Keep away from	nheatorflame
Do Not Use: In	children under 2 months of age	On open skin wounds
with eyes, rinse eyes	od uct keep out of eyes, ears and s thoroughly with water.	
Stop use and aska serious condition	doctorifinitation or rash occurs	. These may be signs of a
Keepout of reach of Control Centerright	of children. If swallowed, get med away.	dical help or contact a Poison
Directions		AND THE PARTY AND
	ct on hands to cover all surfaces. Inder 6 years of age when using t	
Other Information	Store between 15-30C (59- 86F)	Avoid freezing or heat>40C (104F)

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

HAND SANIT	I7FD						
alcohol liquid							
Product Informa	ition						
Product Type		HUMAN OTC DRUG Item Code (Source) NDC:74363-001				NDC:74363-001	
Route of Administr	ation	TOPICAL					
Koute of Auministi	uuun	TOTIONE					
Active Ingredier	t/Activo Moi	n tx					
Acuve ingreuier		•		. .			
	0	lient Name			of Strength	Strength	
ALCOHOL (UNII: 3KS	9958V90M) (ALC	COHOL - UNII:3K9958V90M)		ALCOHO	DL	80 mL in 100 mL	
Inactive Ingredi	ents						
	Ing	gredient Name				Strength	
GLYCERIN (UNII: PD	C6A3C0OX)			1.45 mL in 100 mL			
HYDRO GEN PERO X	I DE (UNII: BBX06	0 AN9 V)		0.125 mL in 100 mL			
WATER (UNII: 059QF	0KO0R)						
Packaging							
# Item Code		Package Description		Marketin	g Start Date	Marketing End Date	
		TLE; Type 0: Not a Combination		04/01/2020	•		
		BOTTLE; Type 0: Not a Combination Product 04/01/2020					
		TLE; Type 0: Not a Combination		04/01/2020)		
		TTLE; Type 0: Not a Combination					
5 NDC:74363-001-05	100 mL in 1 BO	TLE; Type 0: Not a Combinatior	n Product	04/01/2020)		
6 NDC:74363-001-06	500 mL in 1 BO	TTLE; Type 0: Not a Combination	n Product	04/01/2020)		
7 NDC:74363-001-07	750 mL in 1 BO	TTLE; Type 0: Not a Combinatior	n Product	04/01/2020)		
8 NDC:74363-001-08	1000 mL in 1 BC	OTTLE; Type 0: Not a Combination	n Product	04/01/2020)		
o NDC:/4363-001-08	1000 mL in 1 BC	TILE; Type U: Not a Combinatio	on Product	04/01/2020)		

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part333A	04/01/2020			
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date		

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