

80% ALCOHOL HAND SANITIZER- alcohol solution

Phoenix Products 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.

This is a hand rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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 Rub

Use

Health care personnel hand rub 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 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

KMS

* Effective at eliminating 99.9% of many common harmful germs and bacteria.

** Meets the FDA healthcare personnel antiseptic hand rub criteria

Made in USA

Empty &

Discard Pump

PLASTIC BOTTLE

how2recycle.info

Distributed by

KMS, Inc.

811 E Waterman St.

Wichita, KS 67208

SDA-NE-1013

0 79902 07899 8

ALCOHOL ANTISEPTIC 80 % TOPICAL SOLUTION

HAND

SANITIZER

KILLS 99.9% OF GERMS*

FORMULATED FOR HEALTHCARE**




GENTLE ENOUGH FOR EVERYDAY USE

NON-STERILE LIQUID SOLUTION

WARNING FOR EXTERNAL USE ONLY

FLAMMABLE. KEEP AWAY FROM HEAT OR FLAMES

64 FL OZ (1.89 L)

Drug Facts Active ingredient Alcohol 80% v/v.....Antiseptic Purpose Antiseptic	ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION	Drug Facts (continued)
* Effective at eliminating 99.9% of many common harmful germs and bacteria. ** Meets the FDA healthcare personnel antiseptic hand rub criteria	<h1>HAND SANITIZER</h1>	Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
 	<h2>KILLS 99.9% OF GERMS*</h2>	Warnings For external use only. Flammable. Keep away from heat or flame.
Distributed by KIMS, Inc 811 E Waterman St. Wichita, KS 67208	FORMULATED FOR HEALTHCARE** GENTLE ENOUGH FOR EVERYDAY USE NON-STERILE LIQUID SOLUTION WARNING: FOR EXTERNAL USE ONLY FLAMMABLE. KEEP AWAY FROM HEAT OR FLAMES	Do not use • in children less than 2 months of age • on open skin wounds
SDA-NE-1013 	64 FL OZ (1.89 L)	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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Package Label - Principal Display Panel

[Kinnos 8 oz]

kinnos

HAND SANITIZER

8 oz (237mL)

We started this company to protect healthcare workers, patients, and friends and family from infections. At **Kinnos**, our goal is to empower people to protect themselves and others, and to provide society with peace of mind.

Join us at www.kinnos.us

Alcohol Antiseptic
(80%)

Topical solution
Non-sterile

Manufactured by KinnoS Inc.

760 Parkside Avenue, Suite 219

Brooklyn, NY 11226

team@kinnos.us | (978) 314-3127

LB0009 Rev A

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HAND SANITIZER

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(80%)**

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**Topical solution
Non-sterile**

Drug Facts	
Active Ingredient	Purpose
Alcohol 80% v/v.....	Antiseptic
Use	
Hand sanitizer to help reduce bacteria that can potentially 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 	
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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Brooklyn, NY 11226
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LB0009 Rev A

80% ALCOHOL HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73956-301
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)	18.42 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73956-301-64	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:73956-301-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

80% ALCOHOL HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73956-401
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)	18.42 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73956-401-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	06/01/2020	
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Labeler - Phoenix Products Company (101332237)

Establishment

Name	Address	ID/FEI	Business Operations
Phoenix Products Company		101332237	manufacture(73956-301, 73956-401)

Revised: 6/2020

Phoenix Products Company