

HAND SANITIZER- alcohol liquid
Vikre Distillery LLC

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.

Hand Sanitizer

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

48oz NDC:75217-532-07

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution | batch 2

Non-Sterile Solution | 48 OUNCES (1.42L)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	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	
<ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

8OZ NDC: 75217-532-06



HAND SANITIZER

WORLD HEALTH ORGANIZATION RECIPE
WORKS BEST AS A SPRAY | DO NOT DILUTE

Ethanol 80%, Glycerol 1.45%, Hydrogen Peroxide .125%
NOT FOR HUMAN CONSUMPTION
Batched on 4/15/20 • 8 fluid ounces (237 ml)

475mL NDC: 75217-532-01

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 16 FLUID OUNCES (475 ML)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose Antiseptic
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Warnings For external use only. Flammable. Keep away from heat or flame	
Do not use	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 16 FLUID OUNCES (475 ML)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose 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	
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HAND SANITIZER

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Drug Facts	
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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
 Non-Sterile Solution | 1 GAL (3.78L)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	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	
<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.	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 5 GALLONS (18.93 L)

Drug Facts		
Active ingredient(s)	Alcohol 80% v/v	Purpose 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	<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.	
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Inactive ingredients	glycerin, hydrogen peroxide, purified water USP	



HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 5 GALLONS (18.93 L)

Drug Facts		
Active ingredient(s)	Alcohol 80% v/v	Purpose 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	
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HAND SANITIZER

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Drug Facts		
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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 55 GALLONS (208.2 L)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose 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	
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Other information	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 55 GALLONS (208.2 L)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose 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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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | 55 GALLONS (208.2 L)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose 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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1.89L NDC: 75217-532-05

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | HALF GALLON (1.89 L)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose 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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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | HALF GALLON (1.89 L)

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	Purpose 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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HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution
Non-Sterile Solution | HALF GALLON (1.89 L)

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Alcohol Antiseptic 80% Topical Solution
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Drug Facts	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75217-532
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:75217-532-02	3779.99 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75217-532-01	475 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75217-532-03	18930 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75217-532-04	208200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75217-532-05	1889.9 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75217-532-06	236.5882375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75217-532-07	1419.529425 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Vikre Distillery LLC (037081099)

Establishment

Name	Address	ID/FEI	Business Operations
Vikre Distillery LLC		037081099	manufacture(75217-532)

