

HAND SANITIZER- alcohol liquid

Judson & Moore Distillery

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

Drug Facts	
Active ingredient[s] Alcohol 80% v/v.....	PurposeAntiseptic
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.	
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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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Purpose

Antiseptic, Hand Sanitizer

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Package Label - Principal Display Panel

1893 mL NDC: 75781-0001-1

60 mL NDC: 75781-0001-2

LIQUID HAND SANITIZER

**DENATURED ALCOHOL ANTISEPTIC 80%
NON-STERILE, TOPICAL SOLUTION**

WORLD HEALTH ORGANIZATION FORMULA

JUDSON & MOORE

MANUFACTURED 05/2020
JUDSON & MOORE DISTILLERY
CHICAGO, ILLINOIS

2 FL OZ | 60 ML

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JUDSON & MOORE DISTILLERY
CHICAGO, ILLINOIS

0.5 GALLONS | 1.9 L

HAND SANITIZER					
alcohol liquid					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75781-0001		
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					
		Marketing Start	Marketing End		

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75781-0001-1	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	
2	NDC:75781-0001-2	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/02/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/02/2020	

Labeler - Judson & Moore Distillery (040127590)

Establishment			
Name	Address	ID/FEI	Business Operations
Judson & Moore Distillery LLC		040127590	manufacture(75781-0001)