

HAND SANITIZER- alcohol liquid
Clean Pro Supply, 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.

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

3.785 L NDC: 77518-200-01

Drug Facts	
Active Ingredients	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	
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Do Not Use	
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Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer

Non-sterile Solution



**1 Gallon • 128 fl oz • 3785 mL
NDC 77518-200-01**

Questions / Comments:

Call 585-623-5075

Mon - Fri: 8:00am - 4:30pm

Distributed By:

Clean Pro Supply, LLC

1533 Lyell Ave, Rochester, NY 14606



208 L NDC: 77518-200-55

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer

Non-sterile Solution



**55 Gallons • 208L
NDC 77518-200-55**

Drug Facts	
Active Ingredients	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 the 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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HAND SANITIZER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77518-200 (NDC:74663-001)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L	
Inactive Ingredients				
	Ingredient Name	Strength		
	GLYCERIN (UNII: PDC6A3C0OX)			
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)			
	WATER (UNII: 059QF0KO0R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77518-200-01	3.785 L in 1 JUG; Type 0: Not a Combination Product	04/27/2020	

2	NDC:77518-200-55	208 L in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/27/2020		

Labeler - Clean Pro Supply, LLC (039185337)

Establishment			
Name	Address	ID/FEI	Business Operations
Clean Pro Supply, LLC		039185337	relabel(77518-200)

Revised: 5/2020

Clean Pro Supply, LLC