

## **HAND SANITIZER- alcohol liquid**

### **One Ethanol, 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.*

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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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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

18927 mL NDC: 74481-001-01



# Hand Sanitizer

**Alcohol Antiseptic 80% Topical Solution**

**Hand Sanitizer Non-sterile Solution**

5  
Gallons

18927 mL

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**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**

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**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, Denatonium Benzoate, Purified water USP



**NFPA Hazard Classifications**

Health = 1
Fire = 3
Instability = 0

**HMS Hazard Classifications**

Health = 1
Fire = 3
Physical Hazard = 0

204412 mL NDC: 74481-001-02



# Hand Sanitizer

**Alcohol Antiseptic 80% Topical Solution**

**Hand Sanitizer Non-sterile Solution**



204412 mL

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## Drug Facts

### Active ingredient[s]

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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**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 (69-86F)
- Avoid freezing and excessive heat above 40C (104F)

### Inactive Ingredients

Glycerin, Hydrogen Peroxide, Denatonium Benzoate, Purified water USP



### NFPA Hazard Classifications

Health = 1  
Fire = 3  
Instability = 0

### HMIS Hazard Classifications

Health = 1  
Fire = 3  
Physical Hazard = 0

3785 mL NDC: 74481-001-03

3785 mL  
1 Gal



# Hand Sanitizer

**Alcohol Antiseptic 80% Topical Solution**  
**Hand Sanitizer Non-sterile Solution**

## Drug Facts

### Active ingredient[s]

Alcohol 80% v/v .....Antiseptic

### Use[s]

### Purpose

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### **Use**

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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### **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 (69-86F)
- Avoid freezing and excessive heat above 40C (104F)

### **Inactive Ingredients**

Glycerin, Hydrogen Peroxide, Denatonium Benzoate, Purified water USP



#### NFPA Hazard Classifications

Health = 1  
Fire = 3  
Instability = 0

#### HMIS Hazard Classifications

Health = 1  
Fire = 3  
Physical Hazard = 0

One Ethanol, LLC. 1111 O.E. Bieri Industrial Dr. Lowell, MI 49331

946353 mL NDC: 74481-001-04



# Hand Sanitizer

**Alcohol Antiseptic 80% Topical Solution**

**Hand Sanitizer Non-sterile Solution**

250  
Gallons

946353 mL

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## Drug Facts

### Active ingredient[s]

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

- with 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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### 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 (69-86F)
- Avoid freezing and excessive heat above 40C (104F)

### Inactive Ingredients

Glycerin, Hydrogen Peroxide, Denatonium Benzoate, Purified water USP



### NFPA Hazard Classifications

Health = 1  
Fire = 3  
Instability = 0

### HMIS Hazard Classifications

Health = 1  
Fire = 3  
Physical Hazard = 0

## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74481-001
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: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74481-001-01	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74481-001-02	204412 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74481-001-03	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/13/2020	

4	NDC:74481-001-04	946353 mL in 1 TANK; 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** - One Ethanol, LLC (055424996)

**Registrant** - One Ethanol, LLC (055424996)

## Establishment

Name	Address	ID/FEI	Business Operations
One Ethanol, LLC		055424996	manufacture(74481-001)

Revised: 4/2020

One Ethanol, LLC