

**HAND SANITIZER- alcohol liquid**  
**Cotton & Reed, INC.**

*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

60 mL NDC: 7448-001-01

<p><b>Directions</b> • 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.</p> <p><b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)</p> <p><b>Inactive ingredients</b> Glycerin, Hydrogen Peroxide, Purified Water USP</p>	<p>Cotton &amp; Reed WASHINGTON, DC</p> <p><b>HAND SANITIZER</b></p> <p>2 OZ</p>	<p><b>Drug Facts</b></p> <table border="1"><tr><th>Active ingredient</th><th>Purpose</th></tr><tr><td>Alcohol 80% v/v</td><td>Antiseptic, Hand Sanitizer</td></tr></table> <p><b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b> • In children less than 2 months of age • On open skin wounds</p> <p><b>Stop use</b> and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active ingredient	Purpose	Alcohol 80% v/v	Antiseptic, Hand Sanitizer
Active ingredient	Purpose					
Alcohol 80% v/v	Antiseptic, Hand Sanitizer					

60 mL NDC: 7448-001-01 Made in USA

7 42338 99661 6

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473 mL NDC: 7448-001-02

<p><b>Directions</b> • 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.</p> <p><b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)</p> <p><b>Inactive ingredients</b> Glycerin, Hydrogen Peroxide, Purified Water USP</p>	<p>Cotton &amp; Reed WASHINGTON, DC</p> <p><b>HAND SANITIZER</b></p> <p>16 OZ</p>	<p><b>Drug Facts</b></p> <table border="1"><tr><th>Active ingredient</th><th>Purpose</th></tr><tr><td>Alcohol 80% v/v</td><td>Antiseptic, Hand Sanitizer</td></tr></table> <p><b>Uses</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p><b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.</p> <p><b>Do not use</b> • In children less than 2 months of age • On open skin wounds</p> <p><b>Stop use</b> and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active ingredient	Purpose	Alcohol 80% v/v	Antiseptic, Hand Sanitizer
Active ingredient	Purpose					
Alcohol 80% v/v	Antiseptic, Hand Sanitizer					

473 mL NDC: 7448-001-02 Made in USA

7 42338 99660 9

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3875 mL NDC: 7448-001-03

**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, Fragrance (Grapefruit Essential Oil)

Cotton & Reed  
WASHINGTON, DC

# HAND SANITIZER

1 GALLON

## Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v ....	Antiseptic, Hand Sanitizer

**Uses** 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

**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.

3785 mL NDC: 7448-001-03 Made in USA



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750 mL NDC: 7448-001-04

**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

Cotton & Reed  
WASHINGTON, DC

# HAND SANITIZER

25 OZ

## Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v ....	Antiseptic, Hand Sanitizer

**Uses** 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

**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.

750 mL NDC: 7448-001-04 Made in USA



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118 mL NDC: 7448-001-05

**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

Cotton & Reed  
WASHINGTON, DC

# HAND SANITIZER

4 OZ

## Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v ....	Antiseptic, Hand Sanitizer

**Uses** 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

**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.

118 mL NDC: 7448-001-05 Made in USA



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208.2 L NDC: 7448-001-06

**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

208198 mL NDC: 7448-001-05 **Made in USA**



7 42338 99647 0

**Cotton & Reed**  
WASHINGTON, DC

**HAND  
SANITIZER**

55 GAL

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**Drug Facts**

**Active ingredient Purpose**  
Alcohol 80% v/v Antiseptic, Hand Sanitizer

**Uses** 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

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1022 L NDC: 7448-001-07

**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

1022100 mL NDC: 7448-001-07 **Made in USA**



7 42338 99648 7

**Cotton & Reed**  
WASHINGTON, DC

**HAND  
SANITIZER**

270 GAL

cottonandreed.com @cottonandreed

Distributed by Cotton & Reed, INC., Washington, DC 20002

**Drug Facts**

**Active ingredient Purpose**  
Alcohol 80% v/v Antiseptic, Hand Sanitizer

**Uses** 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

**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.

<b>HAND SANITIZER</b>			
alcohol liquid			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74408-001
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)		ALCOHOL	80 mL in 100 mL
<b>Inactive Ingredients</b>			
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:74408-001-01	60 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74408-001-02	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74408-001-03	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74408-001-04	750 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74408-001-05	118.294 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74408-001-06	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
7	NDC:74408-001-07	2081980 mL in 1 BOX; 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** - Cotton & Reed, INC. (080007050)

Establishment			
Name	Address	ID/FEI	Business Operations
Cotton & Reed, INC.		080007050	manufacture(74408-001) , pack(74408-001) , label(74408-001)