

**FORMOCLEAN GEL HAND SANITIZER- alcohol gel**  
**Applichem, 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)**

Medicinal ingredient: Ethyl alcohol 70% 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

Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Triethanolamine, Aloe, Lauryl Alcohol, Myristyl Alcohol, Fragrance (Parfum), PEG Dimethicone

## Package Label - Principal Display Panel

3.8 L NDC: 74751-003-01

**FormoClean**  
For Healthier Cleaner Spaces  
Gel Hand Sanitizer

1 GALLON/3.8L - 70% ALCOHOL - FRESH EUCALYPTUS SCENT

Made in the USA

Drug Facts	
Active ingredient(s)	Propylol Antibiotic
Other ingredient(s)	70% Alcohol
Warnings	Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. For external use only. Flammable. Keep away from heat or flame. Do not use: - on children less than 2 months of age - on open skin wounds When using this product keep out of eyes, nose, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. There 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	- Rub 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 Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Triethanolamine, Lauryl Alcohol, Myristyl Alcohol, Fragrance (Parfum)	



Drug Facts	
Active ingredient(s)	Purpose
Medicinal ingredient: Ethyl alcohol 70% v/v	Antiseptic
<b>Use(s)</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Toluene, Linal Alcohol, Myristyl Alcohol, Fragrance (Parfum)	

HAND SANITIZER NON-STERILE SOLUTION  
ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION

FormoClean, A brand of Applichem Inc  
3211 Nebraska Ave, Suite 300, Council Bluffs, IA 51501

19 L NDC: 74751-003-05



**Gel Hand Sanitizer**

5 GALLONS/19L FRESH EUCALYPTUS SCENT



HAND SANITIZER NON-STERILE SOLUTION  
ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION



Drug Facts	
Active ingredient(s)	Purpose
Medicinal ingredient: Ethyl alcohol 70% v/v	Antiseptic
<b>Use(s)</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 10-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Crosspolymer, Toluene, Linal Alcohol, Myristyl Alcohol, Fragrance (Parfum)	

FormoClean, A brand of Applichem Inc  
3211 Nebraska Ave, Suite 300, Council Bluffs, IA 51501



189 L NDC: 74751-003-50



# FormoClean

For Healthier Cleaner Spaces

## Gel Hand Sanitizer

50 GALLONS/189L FRESH EUCALYPTUS SCENT



HAND SANITIZER NON-STERILE SOLUTION  
ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION



Drug Facts	
Active ingredient(s)	Purpose
Medicinal ingredient: Ethyl alcohol 70% v/v	Antiseptic
<b>Use(s)</b> Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> <ul style="list-style-type: none"> <li>on children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> 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.	
<b>Directions</b> <ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b> <ul style="list-style-type: none"> <li>Store between 10-30C (50-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Copolymer, Toluene, Lauryl Alcohol, Methyl Alcohol, Fragrance (Parfum).	

FormoClean, A brand of Applichem Inc.  
3211 Nebraska Ave, Suite 300, Council Bluffs, IA 51501



250 mL NDC: 74751-003-08



HAND SANITIZER  
NON-STERILE SOLUTION  
ALCOHOL ANTISEPTIC 70%  
TOPICAL SOLUTION

FormoClean  
A brand of Applichem Inc.  
3211 Nebraska Ave, Suite 300  
Council Bluffs, IA 51501



3 74751 00006 1



# FormoClean

For Healthier Cleaner Spaces

## Gel Hand Sanitizer



8 FL OZ/236 mL - 70% ALCOHOL  
FRESH EUCALYPTUS SCENT



**Drug Facts**

Active ingredient(s) Purpose  
Medicinal ingredient: Ethyl alcohol 70% 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**  

- on 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**  

- 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 10-30C (50-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients** Water (Aqua), Glycerin, Hydrogen Peroxide, Alkyl Acrylate Copolymer, Toluene, Lauryl Alcohol, Methyl Alcohol, Fragrance (Parfum)

500 mL NDC: 74751-003-16



HAND SANITIZER  
NON-STERILE SOLUTION  
ALCOHOL ANTISEPTIC 70%  
TOPICAL SOLUTION

FormoClean  
A brand of Applichem Inc.  
3211 Nebraska Ave, Suite 300  
Council Bluffs, IA 51501



**FormoClean**  
For Healthier Cleaner Spaces



16.9 FL. OZ/500 mL - 70% ALCOHOL  
FRESH EUCALYPTUS SCENT



Made in the USA

Drug Facts	
Active ingredient(s)	Purpose
National ingredient: Ethyl alcohol 70% v/v	antiseptic
Indication	
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	
- in 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. There 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: Water, Glycerin, Hydrogen Peroxide, Methylcellulose, Carbomer, Triethyl Citrate, Methyl Cellulose, Fragrance, Potassium Sorbate	

## FORMOCLEAN GEL HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74751-004
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70.6586 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.3344 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.1258 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.6023 mL in 100 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	7.6152 mL in 100 mL
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	0.0216 mL in 100 mL
MYRISTYL LACTATE (UNII: 1D822OC34X)	0.2656 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.2665 mL in 100 mL
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	0.0187 mL in 100 mL

### Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74751-004-01	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74751-004-05	19000 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74751-004-50	190000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74751-004-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74751-004-16	500 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** - Applichem, Inc (039829528)

Revised: 11/2020

Applichem, Inc