

**KLEENSWELL GEL HAND SANITIZER- alcohol gel**  
**Hygienic Labs, 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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**KLEENSWELL GEL HAND SANITIZER - 70% alcohol gel**  
**Hygienic Labs, 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 hand sanitizer is manufactured using United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation).

**Active Ingredients**

Medicinal ingredient: Ethyl alcohol 70% v/v..... Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce viruses and 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.

**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)

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

**Package Label - Principal Product Label**

3800 mL NDC: 79692-003-01

**Drug Facts**

Active ingredient(s)	Purpose
Medicinal ingredient: Ethyl alcohol 70% v/v	Antiseptic
<b>Uses</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.	
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. 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.	
<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.	
<b>Other information</b>	
• 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	

19000 mL NDC: 79692-003-05

**Drug Facts**

Active ingredient(s)	Purpose
Medicinal ingredient: Ethyl alcohol 70% v/v	Antiseptic
<b>Uses</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.	
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. 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.	
<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.	
<b>Other information</b>	
• 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	

189000 mL NDC: 79692-003-50



# KleenSwell™

## Gel Hand Sanitizer with Aloe

### Your Virus Protection Guardian Angel

*Proven to kill 99.9% of common germs*

50 GALLONS/189L - LEMONGRASS SCENT







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



Made in the USA



**Drug Facts**

Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

**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**

- 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.

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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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 43°C (109°F)

Active ingredient: Water (Aqua), Glycerin, Hydrogen Peroxide, Aloy-Aloeol, Cocospolymer, Tetrahydrofuran, Hex. Linalyl Alcohol, Methyl Alcohol, Fragrance (Parfum), PEG Dimethicone

Manufactured by:  
**Hygienic Labs, LLC.**  
3211 Nebraska Ave. Ste 300  
Council Bluffs, IA 51501  
(833) FPE-PLUS  
www.KleenSwell.com



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250 mL NDC: 79692-003-08



KLEENSWELL  
NON-STERILE SOLUTION  
ALCOHOL ANTISEPTIC 70%  
TOPICAL SOLUTION

KleenSwell™ is owned by Hygienic Labs, LLC  
3211 Nebraska Ave. Ste 300, Council Bluffs, IA 51501  
(833) FPE-PLUS | www.KleenSwell.com



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## Gel Hand Sanitizer with Aloe

### Your Virus Protection Guardian Angel

*Proven to kill 99.9% of common germs*







50 GALLONS/189L - LEMONGRASS SCENT



**Drug Facts**

Active ingredient(s)	Purpose
Alcohol 70% v/v	Antiseptic

**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**

- 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.

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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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 43°C (109°F)

Active ingredient: Water (Aqua), Glycerin, Hydrogen Peroxide, Aloy-Aloeol, Cocospolymer, Tetrahydrofuran, Hex. Linalyl Alcohol, Methyl Alcohol, Fragrance (Parfum), PEG Dimethicone

500 mL NDC: 79692-003-16



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

KleenSwell™ a brand of  
Hygienic Labs, LLC.  
3211 Nebraska Ave, Suite 300  
Council Bluffs, IA 51501  
(833) PPE-PLUS | www.KleenSwell.com



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## Gel Hand Sanitizer with Aloe

Your Virus Protection Guardian Angel

Proven to kill 99.9% of common germs



16.9 FL OZ/500 mL - 70% ALCOHOL - LEMONGRASS SCENT



Made in USA

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	
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Directions	
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- Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information	
- Store between 15-30°C (59-86°F)	
- Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients: Water (Aqua), Glycerin, Hydrogen Peroxide, ACRYLATE COPOLYMER, Triethanolamine, Aloe, Linalyl Alcohol, Myristyl Alcohol, Fragrance (Parfum), PEG Dimethicone	

## KLEENSWELL GEL HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79692-003
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
TROLAMINE (UNII: 9O3K93S3TK)	0.6023 mL in 100 mL
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	0.0187 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.2665 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.1258 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
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.3344 mL in 100 mL

### Packaging

	Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79692-003-01	3800 mL in 1 JUG; Type 0: Not a Combination Product	08/15/2020	
2	NDC:79692-003-50	189000 mL in 1 DRUM; Type 0: Not a Combination Product	08/15/2020	
3	NDC:79692-003-05	19000 mL in 1 PAIL; Type 0: Not a Combination Product	08/15/2020	
4	NDC:79692-003-08	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020	
5	NDC:79692-003-16	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/15/2020	

**Labeler** - Hygienic Labs, LLC. (117590193)

## Establishment

Name	Address	ID/FEI	Business Operations
Hygienic Labs, LLC.		117580036	label(79692-003) , repack(79692-003)

## Establishment

Name	Address	ID/FEI	Business Operations
Hygienic Labs, LLC.		117590193	label(79692-003) , manufacture(79692-003)

Revised: 12/2020

Hygienic Labs, LLC.