

HAND SANITIZER- alcohol gel
FRSH HANDS 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.

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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. Glycerin (1.45% v/v).
- c. Carbopol 940.
- d. Triethanolamine
- e. Essential Oil
- f. Sterile distilled water or boiled cold water.

Active Ingredient(s)

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.

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

Distilled Water, Carbopol 940, Glycerin, Triethanolamine, Essential Oil

Package Label - Principal Display Panel

59.147 mL NDC: 78217-002-01

FRSH HANDS START HERE

FRSH HANDS™

ETHYL ALCOHOL 70%

HAND SANITIZER

ANTISEPTIC TOPICAL GEL

MADE IN THE USA
2 FL OZ - 59.147 mL

Drug Facts	
Active Ingredient[s] Ethyl Alcohol 70%	Purpose 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">• 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 <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°-30°C (59°-86°F)• Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients Distilled Water, Carbopol 940, Glycerin, Triethanolamine, Essential Oil	

For more information please visit FRSHHANDS.COM

8 60003 90827 3

118.294 mL NDC: 78217-002-02

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ETHYL ALCOHOL 70%

HAND SANITIZER

ANTISEPTIC TOPICAL GEL



MADE IN THE USA
4 FL OZ - 118.294 mL

Drug Facts

Active Ingredient[s]	Purpose
Ethyl Alcohol 70%	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 15°-30°C (59°-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
Distilled Water, Carbopol 940, Glycerin, Triethanolamine, Essential Oil

For more information please visit FRSHHANDS.COM



236.59 mL NDC: 78217-002-03

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ETHYL ALCOHOL 70%

HAND SANITIZER

ANTISEPTIC TOPICAL GEL



MADE IN THE USA
8 FL OZ - 236.59 mL

Drug Facts

Active Ingredient[s]	Purpose
Ethyl Alcohol 70%	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 15°-30°C (59°-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
Distilled Water, Carbopol 940, Glycerin, Triethanolamine, Essential Oil

For more information please visit FRSHHANDS.COM



473.176 mL NDC: 78217-002-04

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ETHYL ALCOHOL 70%

HAND SANITIZER

ANTISEPTIC TOPICAL GEL



MADE IN THE USA
16 FL OZ - 473.176 mL

Drug Facts

Active Ingredients[s]	Purpose
Ethyl Alcohol 70%	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 15°-30°C (59°-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients
Distilled Water, Carbopol 940, Glycerin, Triethanolamine, Essential Oil

For more information please visit FRSHHANDS.COM



3785 mL NDC: 78217-002-05

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ETHYL ALCOHOL 70%

HAND SANITIZER

ANTISEPTIC TOPICAL GEL



MADE IN THE USA
1 Gallon - (3.78L)

Drug Facts

Active Ingredients[s]	Purpose
Ethyl Alcohol 70%	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.

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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
Distilled Water, Carbopol 940, Glycerin, Triethanolamine, Essential Oil

For more information please visit FRSHHANDS.COM



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78217-002(NDC:77808-002)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
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:78217-002-01	59.147 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2020	
2	NDC:78217-002-02	118.294 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2020	
3	NDC:78217-002-03	236.59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2020	
4	NDC:78217-002-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2020	
5	NDC:78217-002-05	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/20/2020	

Labeler - FRSH HANDS LLC (117524588)

Revised: 7/2020

FRSHHANDS LLC