

GEL HAND SANITIZER- alcohol gel
5 Peaks Products, 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.

70% Gel Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

To help reduce bacteria on skin.

Warnings

For external use only. Flammable, keep away from source of heat & fire.

When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use & ask doctor if irritation occurs or redness develops & persists.

Keep out of reach of children. In case of accidental ingestion, seek medical help and contact a Poison Control Center Immediately.

Directions

Put enough hand sanitizer on your palm to cover hands & rub hands together until dry. Children under 5 should be supervised using this product.

Inactive ingredients

Water (Aqua, Eau), Glycerin, Liquid Preneutralized Thickener/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate.

Package Label - Principal Display Panel



ALOE + SQUALANE

KILLS
99.9%
OF GERMS*

ANTI-BACTERIAL
DYE-FREE

70%
ALCOHOL

Net Wt. 3.4 oz (100 mL)



DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use & ask doctor if irritatin occurs or redness develops & persists.	
Keep out of reach of children. In case of accidental ingestion, seek medical help and contact a Poison Control Center Immediately.	
Directions: Put enough hand sanitizer on your palm to cover hands & rub hands together until dry. Children under 5 should be supervised using this product.	

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.



*DISCLAIMERS AND CLAIMS INFORMATION CAN BE FOUND ON OUR WEBSITE

Distributed by:
5 Peaks Products LLC
 132 Forest Ave NE
 Marietta, GA 30060 USA
www.5peaksproducts.com



NDC : 80242-100-01



ALOE + SQUALANE



ANTI-BACTERIAL
DYE-FREE



Net Wt. 8.45 oz (250 mL)



DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
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NDC : 80242-100-02



ALOE + SQUALANE

KILLS
99.9%
OF GERMS*

ANTI-BACTERIAL
DYE-FREE

70%
ALCOHOL

Net Wt. 16.9 oz (500 mL)



DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use & ask doctor if irritatin occurs or redness develops & persists.	
Keep out of reach of children. In case of accidental ingestion, seek medical help and contact a Poison Control Center Immediately.	
Directions: Put enough hand sanitizer on your palm to cover hands & rub hands together until dry. Children under 5 should be supervised using this product.	

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadosis Leaf Juice, Tocopheryl Acetate.



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NDC : 80242-100-03



DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use & ask doctor if irritaiton occurs or redness develops & persists.	
Keep out of reach of children. In case of accidental ingestion, seek medical help and contact a Poison Control Center Immediately.	
Directions: Put enough hand sanitizer on your palm to cover hands & rub hands together until dry. Children under 5 should be supervised using this product.	

NDC - 80242-100-04



ALOE + SQUALANE



Net Wt. 1 Liter (33 oz)



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 Marietta, GA 30060 USA
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Net Wt. 1 GALLON (3.785 L)

DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use & ask doctor if irritaiton occurs or redness develops & persists.	
Keep out of reach of children. In case of accidental ingestion, seek medical help and contact a Poison Control Center Immediately.	
Directions: Put enough hand sanitizer on your palm to cover hands & rub hands together until dry. Children under 5 should be supervised using this product.	

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

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NDC - 80242-100-04



70%
Alcohol



Kills 99.9%
of germs*



Hydrates
& Protects



Paraben
Free



Dye Free
Formulation



Cruelty
Free

DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
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RECYCLABLE



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NDC : 80242-100-06



ALOE+SQUALANE



ANTI-BACTERIAL

DYE-FREE



Net Wt. 55 Gallons (208 L)



70%
Alcohol



Kills 99.9%
of germs*



Hydrates
& Protects



Paraben
Free



Dye Free
Formulation



Cruelty
Free

DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
Flammable, keep away from source of heat & fire.	
When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use & ask doctor if irritatin occurs or redness develops & persists.	
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Directions: Put enough hand sanitizer on your palm to cover hands & rub hands together until dry. Children under 5 should be supervised using this product.	

NDC : 80242-100-07

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.

ALOE+SQUALANE

☑ ANTI-BACTERIAL
☑ DYE-FREE

KILLS 99.9% OF GERMS*

70% ALCOHOL

Net Wt. 265 Gallon (1000 L)



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- 100 mL NDC: 80242-100-01
- 250 mL NDC: 80242-100-02
- 500 mL NDC: 80242-100-03
- 1 L NDC: 80242-100-04
- 3.785 L NDC: 80242-100-05
- 208 L NDC: 80242-100-06
- 1000 L NDC: 80242-100-07

iUnderstand Product Label

i understand
love heals

GEL HAND SANITIZER

LOVE HEALS
LOVE HEALS
LOVE HEALS
LOVE HEALS
LOVE HEALS
LOVE HEALS
LOVE HEALS

www.iunderstandloveheals.org

 iunderstand_loveheals

 iunderstandloveheals



ALOE + SQUALANE

KILLS 99.9% OF GERMS **ANTI-BACTERIAL** **70% ALCOHOL**
DYE-FREE

Net Wt. 8.45 oz (250 mL)



DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
Warnings: For external use only.	
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NDC : 80242-100-02

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbardensis Leaf Juice, Tocopheryl Acetate.



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i understand
love heals

GEL HAND SANITIZER

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LOVE HEALS
LOVE HEALS
LOVE HEALS
LOVE HEALS

www.iunderstandloveheals.org

 iunderstand_loveheals

 iunderstandloveheals



ALOE + SQUALANE

KILLS 99.9% OF GERMS **ANTI-BACTERIAL** **70% ALCOHOL**
DYE-FREE

Net Wt. 16.9 oz (500 mL)



DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v Gel.....	Antiseptic
Use: To help reduce bacteria on skin.	
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NDC : 80242-100-03

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadensis Leaf Juice, Tocopheryl Acetate.



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i understand
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GEL HAND SANITIZER

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LOVE HEALS

www.iunderstandloveheals.org

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DRUG FACTS

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NDC : 80242-100-04

Inactive Ingredients: Water (Aqua, Eau) Glycerin Liquid Preneutralized Thickner/Emulsifier, Squalane, Fragrance (Parfum), Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate.



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250 mL NDC: 80242-100-02

500 mL NDC: 80242-100-03

1 L NDC: 80242-100-04

GEL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80242-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SQUALANE (UNII: GW89575KF9)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80242-100-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	09/01/2020	
2	NDC:80242-100-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
3	NDC:80242-100-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
4	NDC:80242-100-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
5	NDC:80242-100-05	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	
6	NDC:80242-100-06	208000 mL in 1 DRUM; Type 0: Not a Combination Product	09/01/2020	
7	NDC:80242-100-07	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - 5 Peaks Products, LLC (117631506)

Registrant - 5 Peaks Products, LLC (117631506)

Revised: 9/2020

5 Peaks Products, LLC