ESSENTIALS BY CATALINA HAND SANITIZER- alcohol liquid Maki Creations, 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.

Essentials by Catalina Hand Sanitizer Gel

Active Ingredients[s]

Alcohol 70% v/v

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

- 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 thoroughtly 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

Deionized Water, Glycerin, Propylene Glycol, Organic Aloe Barbadensis (Aloe Vera) Leaf Extract, Panthenol (Pro-Vitamin B5), Tocopheryl Acetate (Vitamin E Acetate), Carbomer

Proudly made in the USA with 97% American materials



PRESERVATIVE-FREE ● ALOE VERA ● DRIES FAST ● PRO-VITAMIN B5 ● VITAMIN E

ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION

NON-STERILE SOLUTION

FRAGRANCE FREE

1 Tote / 275 Gallons / 1,040,987 ml

Drug Facts

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Panthenol (Pro-Vitamin B5), Tocopheryl Acetate (Vitamin E Acetate)
Carthomer









12781 Temescal Canyon Rd, Corona

Phone: (951) 674-4444

NDC 76902-025-05 www.essentialsbycatalina.com

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PRESERVATIVE-FREE ● ALOE VERA ● DRIES FAST ● PRO-VITAMIN B5 ● VITAMIN E

ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION

NON-STERILE SOLUTION

FRAGRANCE FREE

55 Gallons / 208,197 ml

Drug Facts

Active ingredient[s]

Alcohol 70% v/v ...

Antiseptic

Use[s]

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PRESERVATIVE-FREE ● ALOE VERA ● DRIES FAST ● PRO-VITAMIN B5 ● VITAMIN E

ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION

NON-STERILE SOLUTION

FRAGRANCE FREE

5 Gallons / 18,927 ml

Drug Facts

Active ingredient[s]

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NDC 76902-025-03

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HAND SANITIZER GEL

PRESERVATIVE-FREE ● ALOE VERA ● DRIES FAST ● PRO-VITAMIN B5 ● VITAMIN E

ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION

NON-STERILE SOLUTION

FRAGRANCE FREE

1 Gallon / 3785 ml

Drug Facts

Active ingredient[s]

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NDC 76902-025-02

Phone: (951) 674-4444

MAKI CREATIONS INC

www.essentialsbycatalina.com

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ESSENTIALS BY CATALINA HAND SANITIZER

alcohol liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:76902-025 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		
POLYQUATERNIUM-37 (3000 MPA.S) (UNII: HU373G0YSU)	0.62 mL in 100 mL		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.18 mL in 100 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.8 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	1.32 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.02 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	27.06 mL in 100 mL		
PANTHENOL (UNII: WV9CM0O67Z)	0.01 mL in 100 mL		
.ALPHATO CO PHERO L ACETATE, D- (UNII: A7E6112E4N)	0.01 mL in 100 mL		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76902-025-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020		
2	NDC:76902-025- 02	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/11/2020		
3	NDC:76902-025- 03	18927 mL in 1 PAIL; Type 0: Not a Combination Product	05/11/2020		
4	NDC:76902-025- 04	208197 mL in 1 DRUM; Type 0: Not a Combination Product	05/11/2020		
5	NDC:76902-025- 05	1040987 mL in 1 TANK; Type 0: Not a Combination Product	05/11/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/11/2020			

Labeler - Maki Creations, Inc. (080478763)

Establishment				
Name	Address	ID/FEI	Business Operations	
Maki Creations, Inc.		080478763	manufacture(76902-025)	

Revised: 5/2020 Maki Creations, Inc.