

ESSENTIALS BY CATALINA HAND SANITIZER GEL- alcohol liquid

Maki Creations

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 Ingredient[s]

Alcohol 80% v/v

Purpose

Antiseptic

Uses[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 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, Aminomethyl Propanol

Proudly made in the USA
with 97% American materials



70%
ALCOHOL

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

5 Gallons / 18,927 ml

Drug Facts

Active ingredient[s]	Purpose
Alcohol 70% v/v	Antiseptic

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Questions? (951) 674-4444



MAKI CREATIONS INC
12781 Temescal Canyon Rd, Corona,
CA 92883
Phone: (951) 674-4444

NDC 76902-027-03

www.essentialscatalina.com

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TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

55 Gallons / 208,197 ml

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ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

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

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70%
ALCOHOL

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ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

8 oz / 236 ml

Drug Facts

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NDC 76902-027-01

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ESSENTIALS BY
CATALINA
BATH AND BODY CREATIONS

70%
ALCOHOL

HAND SANITIZER GEL

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ALCOHOL ANTISEPTIC 70%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

1 Gallon / 3785 ml

Drug Facts

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NDC 76902-027-02

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DISTRIBUTED BY ESSENTIALS BY CATALINA

ESSENTIALS BY CATALINA HAND SANITIZER GEL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76902-027
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
WATER (UNII: 059QF0KO0R)	25.852 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.841 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.381 mL in 100 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.007 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.009 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.373 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.009 g in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1.515 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76902-027-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
2	NDC:76902-027-02	3785 mL in 1 JUG; Type 0: Not a Combination Product	06/04/2020	
3	NDC:76902-027-03	18927 mL in 1 PAIL; Type 0: Not a Combination Product	06/04/2020	
4	NDC:76902-027-04	208197 mL in 1 DRUM; Type 0: Not a Combination Product	06/04/2020	
5	NDC:76902-027-05	1040987 mL in 1 TANK; Type 0: Not a Combination Product	06/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/04/2020	

Labeler - Maki Creations (080478763)

Establishment

Name	Address	ID/FEI	Business Operations
Maki Creations, Inc.		080478763	manufacture(76902-027)

Revised: 6/2020

Maki Creations