

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 Spray

Active Ingredient[s]

Alcohol 80% 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 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, Aloe Barbadosis (Aloe Vera) Leaf Extract, Panthenol (Pro-Vitamin B5), Tocopheryl Acetate (Vitamin E Acetate)

Proudly made in the USA
with 97% American materials



80%
ALCOHOL

HAND SANITIZER SPRAY

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

ALCOHOL ANTISEPTIC 80%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

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

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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

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



NDC 76902-026-05

www.essentialshycatalina.com

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

MANUFACTURED BY MAKI CREATIONS INC
DISTRIBUTED BY ESSENTIALS BY CATALINA

Proudly made in the USA
with 97% American materials



80%
ALCOHOL

HAND SANITIZER SPRAY

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

ALCOHOL ANTISEPTIC 80%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

55 Gallons / 208,197 ml

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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

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



NDC 76902-026-04

www.essentialshycatalina.com

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

MANUFACTURED BY MAKI CREATIONS INC
DISTRIBUTED BY ESSENTIALS BY CATALINA

Proudly made in the USA
with 97% American materials



80%
ALCOHOL

HAND SANITIZER SPRAY

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

ALCOHOL ANTISEPTIC 80%

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 80% 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**
- 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 Deionized Water, Glycerin, Propylene Glycol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Panthenol (Pro-Vitamin B5), Tocopheryl Acetate (Vitamin E Acetate)



Questions? (951) 674-4444



NDC 76902-026-03

www.essentialshycatalina.com

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

MANUFACTURED BY MAKI CREATIONS INC
DISTRIBUTED BY ESSENTIALS BY SCATALINA

Proudly made in the USA
with 97% American materials



80%
ALCOHOL

HAND SANITIZER SPRAY

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

ALCOHOL ANTISEPTIC 80%

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

1 Gallon / 3785 ml

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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**
- 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 Deionized Water, Glycerin, Propylene Glycol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Panthenol (Pro-Vitamin B5), Tocopheryl Acetate (Vitamin E Acetate)



Questions? (951) 674-4444



NDC 76902-026-02

www.essentialshycatalina.com

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

MANUFACTURED BY MAKI CREATIONS INC
DISTRIBUTED BY ESSENTIALS BY SCATALINA

Proudly made in the USA
with 97% American materials

ESSENTIALS BY
CATALINA
BATH AND BODY CREATIONS

**80%
ALCOHOL**

**HAND
SANITIZER
SPRAY**

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

**ALCOHOL
ANTISEPTIC 80%**

KILLS MOST HARMFUL GERMS AND BACTERIA

TOPICAL SOLUTION
NON-STERILE SOLUTION

FRAGRANCE FREE

8 oz / 236 ml

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% 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	
<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 Deionized Water, Glycerin, Propylene Glycol, Aloe Barbadensis (Aloe Vera) Leaf Extract, Panthenol (Pro-Vitamin B5), Tocopheryl Acetate (Vitamin E Acetate)	



Questions? (951) 674-4444

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

NDC 76902-026-01

www.essentialshycatalina.com

MANUFACTURED BY MAKI CREATIONS INC
DISTRIBUTED BY ESSENTIALS BY CATALINA

ESSENTIALS BY CATALINA HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76902-026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	15.817 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.009 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3.335 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.812 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.021 mL in 100 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.007 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End Date
---	-----------	---------------------	-----------------	--------------------

#	Item Code	Package Description	Date	Marketing End Date
1	NDC:76902-026-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
2	NDC:76902-026-02	3785 mL in 1 JUG; Type 0: Not a Combination Product	05/18/2020	
3	NDC:76902-026-03	18927 mL in 1 PAIL; Type 0: Not a Combination Product	05/18/2020	
4	NDC:76902-026-04	208197 mL in 1 DRUM; Type 0: Not a Combination Product	05/18/2020	
5	NDC:76902-026-05	1040987 mL in 1 TANK; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - Maki Creations, Inc. (080478763)

Establishment

Name	Address	ID/FEI	Business Operations
Maki Creations, Inc.		080478763	manufacture(76902-026)

Revised: 5/2020

Maki Creations, Inc.