

## **CARE 1- hand sanitizer gel**

**Lauree 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.*

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### **Care1 2oz OTC Coconut Lemongrass and Lavender**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Alcohol 80% 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.

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### 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

glycerin, coconut, aloe, propanediol, hydroxypropyl cellulose, cymbopogon citratus leaf, purified water USP, tert-butyl alcohol

<b>PRODUCT INFO</b> 	<b>care 1</b> <b>HAND SANITIZER</b>	<b>DRUG FACTS</b>				
	<b>COCONUT LEMONGRASS SCENTED</b>	<table border="1"><thead><tr><th>ACTIVE INGREDIENT</th><th>PURPOSE</th></tr></thead><tbody><tr><td>Ethyl Alcohol 72% v/v</td><td>Antiseptic</td></tr></tbody></table>	ACTIVE INGREDIENT	PURPOSE	Ethyl Alcohol 72% v/v	Antiseptic
ACTIVE INGREDIENT	PURPOSE					
Ethyl Alcohol 72% v/v	Antiseptic					
NDC XXXXXXXXXXXX	 <b>Made in the USA</b> 72% Ethyl Alcohol	<b>USES</b> To help reduce bacteria that potentially can cause disease. For use when soap and water are not available.				
	<b>Kills 99.9% Germs Without Soap &amp; Water</b>	<b>WARNINGS</b> For external use only, primarily on the skin of the hands. Avoid contact with eyes. If contact occurs, rinse thoroughly with water.				
Visit us at care1medical.life	Advanced Gel with Aloe Vera	<b>FLAMMABLE, KEEP AWAY FROM FIRE</b>				
Distributed by: Care 1 Medical 11770 Warner Avenue #111 Fountain Valley, CA 92708 (949) 459-3645	<b>NET 2 FL OZ</b>	<b>STOP USE AND ASK A DOCTOR</b> If rash or irritation or redness develops and lasts				
		<b>KEEP OUT OF REACH OF CHILDREN</b> If product is swallowed, get medical help or contact a Poison Control Center right away.				
		<b>OTHER INFORMATION</b> Store below 110°F (43°C) May discolor certain fabrics or surfaces.				
		<b>INACTIVE INGREDIENTS</b> Water, Propylene Glycol, Hydroxyethyl Cellulose, Glycerin, tert-Butyl Alcohol, Aloe Vera, Fragrance.				
		 8 60005 50452 7				

Package Label - Principal Display Panel

**PRODUCT INFO**





# HAND SANITIZER

**COCONUT LEMONGRASS SCENTED**

NDC XXXXXXXXXXXXX

Made in the USA  
72% Ethyl Alcohol

**Kills 99.9% Germs Without Soap & Water**

Advanced Gel with Aloe Vera

NET 2 FL OZ

**DRUG FACTS**

ACTIVE INGREDIENT	PURPOSE
Ethyl Alcohol 72% v/v	Antiseptic

**USES**  
To help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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Water, Propylene Glycol, Hydroxyethyl Cellulose, Glycerin, tert-Butyl Alcohol, Aloe Vera, Fragrance.

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59 mL NDC:78975-506-01

**PRODUCT INFO**





# HAND SANITIZER

**LAVENDER SCENTED**

NDC XXXXXXXXXXXXX

Made in the USA  
72% Ethyl Alcohol

**Kills 99.9% Germs Without Soap & Water**

Advanced Gel with Aloe Vera

NET 2 FL OZ

**DRUG FACTS**

ACTIVE INGREDIENT	PURPOSE
Ethyl Alcohol 72% v/v	Antiseptic

**USES**  
To help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**WARNINGS**  
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59 mL NDC:78975-507-02

## CARE 1

hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78975-506
<b>Route of Administration</b>	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
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.125 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	0.125 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	
COCONUT (UNII: 3RT3536DHY)	0.5 mL in 100 mL
CYMOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	0.5 mL in 100 mL

### Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78975-506-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/06/2020	



**PRODUCT INFO**



# HAND SANITIZER

COCONUT LEMONGRASS SCENTED

Made in the USA  
72% Ethyl Alcohol

**Kills 99.9% Germs Without Soap & Water**

Advanced Gel with Aloe Vera

NET 2 FL OZ

**DRUG FACTS**

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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/06/2020	

## CARE 1

hand sanitizer gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78975-507
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	47 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	0.125 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.125 mL in 100 mL
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.5 mL in 100 mL

### Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78975-507-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/06/2020	





care1  
**HAND  
SANITIZER**

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72% Ethyl Alcohol

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OTC monograph not final	part333A	11/06/2020	

**Labeler** - Lauree LLC (102938225)

**Registrant** - Care 1 (066368393)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lauree LLC		102938225	manufacture(78975-506, 78975-507)