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.

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.

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, TERT-BUTYL ALCOHOL, purified water USP, HYDROXYPROPYL CELLULOSE, 1,2-PROPANEDIOL, ALOE

1000 ml Care1 Citrus

1000 ml Care1 Coconut Lemongrass

- FDA Cleared
- Sulfate-Free
- Paraben-Free
- BPA-Free

crueltyfree andvegan

care 1

HAND SANITIZER

COCONUT LEMONGRASS SCENTED

Made in the USA

72% Ethyl Alcohol

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
For external use only, primarily on the skin of the hands.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

FLAMMABLE, KEEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR
If rash or irritation or redness develops and lasts

KEEP OUT OF REACH OF CHILDREN
If product is swallowed, get medical help or contact a Poison Control Center right away.

OTHER INFORMATION
Store below 110°F (43°C)
May discolor certain fabrics or surfaces.

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

PRODUCT INFO

Visit us at
care1medical.life

Distributed by:
Care 1 Medical
11770 Warner Avenue #111
Fountain Valley, CA 92708
(949) 459-3445

Kills 99.99% Germs Without Soap & Water

Advanced Gel with Aloe Vera

NET 33.8 FL OZ (1 L)

8 60004 55794 4

3785 ml Care1 Citrus

- FDA Cleared
- Sulfate-Free
- Paraben-Free
- BPA-Free

crueltyfree andvegan

care 1

HAND SANITIZER

CITRUS SCENTED

Made in the USA

72% Ethyl Alcohol

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
For external use only, primarily on the skin of the hands.

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

FLAMMABLE, KEEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR
If rash or irritation or redness develops and lasts

KEEP OUT OF REACH OF CHILDREN
If product is swallowed, get medical help or contact a Poison Control Center right away.

OTHER INFORMATION
Store below 110°F (43°C)
May discolor certain fabrics or surfaces.

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

PRODUCT INFO

Visit us at
care1medical.life

Distributed by:
Care 1 Medical
11770 Warner Avenue #111
Fountain Valley, CA 92708
(949) 459-3445

Kills 99.99% Germs Without Soap & Water

Advanced Gel with Aloe Vera

NET 128 FL OZ (1 GAL) 3.78L

8 60004 55799 9

3785 ml Care1 Coconut Lemongrass

CARE 1

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78975-501
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**
CITRUS FRUIT (UNII: XDK00Z8012)	1 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	80 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.125 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:78975-501-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

CARE 1

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78975-502
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
CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	0.5 mL in 100 mL
COCONUT (UNII: 3RT3536DHY)	0.5 mL in 100 mL

ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	0.125 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:78975-502-02	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

CARE 1

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78975-503
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
CITRUS FRUIT (UNII: XDK00Z8012)	1 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	80 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.125 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:78975-503-03	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

CARE 1

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78975-504
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

CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5)	0.5 mL in 100 mL
COCONUT (UNII: 3RT3536DHY)	0.5 mL in 100 mL
ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	0.125 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:78975-504-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - LAUREE LLC (102938225)

Registrant - Care 1 (066368393)

Establishment

Name	Address	ID/FEI	Business Operations
Lauree LLC		102938225	manufacture(78975-501, 78975-502, 78975-503, 78975-504)

Revised: 9/2020 LAUREE LLC