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

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

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









DRUG FACTS

ACTIVE INGREDIENT PURPOSE Bityl Aloshol 72% v/v.....

USES

To help reduce besterie that potentially on ourse disease. For use when soop and water are not available.

WARNINGS

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

Avoid contact with eyes. If contact occurs, times theroughly with water.

FLAMMABLE, KEEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR

KEEP OUT OF REACH OF CHILDREN If product in mediawed, get medical help or contact a Poleon Control Center right away.

OTHER REPORTATION Store below 110°F (45°C) May discolor certain fabrics or surfaces

NACTIVE MOREDIENTS Water, Propriete Glycol, Hydrograftyl Callulose, Glyceth, Ierl-Bulyl Alechol, Alec



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Distributed by: Care 1 Medical 11770 Warner Avenue #111 Fountain Valley, CA 92708 (949) 459-3645

Kills 99.99% Germs Without Soap & Water

Advanced Gel with Aloe Vera

NET 33.8 FL QZ (1 L)



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







Made in the USA 72% Ethyl Alcohol

DRUG FACTS

ACTIVE MIGREDIENT **PURPOSE** Bityl Alochol 72% v/v......

USES

To help restuce becarie that potentially care cause disease. For use when soop and water are not available.

WARNINGS

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

Avoid contact with eyes, if contact occurs, times theroughly with water.

FLAMMABLE, REEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR

KEET OUT OF REACH OF CHILDREN
If product is resilicated, get resilicated pro-contact a Poleon Control Center right away.

OTHER REPORTATION Store below 110°F (45°C) May discolor sertain fabrics or surface

NACTIVE NOREDENTS

Water, Propriete Glycol, Hydrosyethyl Cellulose, Glyceth, tert-Butyl Alachol, Aloe



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Kills 99.99% Germs Without Soap & Water

Advanced Gel with Aloe Vera

NET 33.8 FL OZ (1 L)



3785 ml Care1 Citrus

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



PRODUCT

Visit us at care1 medical.ife Distributed by: Care 1 Medical 11770 Warner Avenue #111 Fountain Valley, CA 92708 (949) 459-3445



Made in the USA 72% Ethyl Alcohol

Kills 99.99% Germs Without Soap & Water Advanced Gel with Aloe Vera

NET 128 FL OZ (1 GAL) 3.78L

DRUG FACTS

ACTIVE INGREDIENT PURPOSE

To help reduce besterin that potentially can amount disease. For use when some and water are not enalistic.

WARNINGS

For external use only, primerily on the akin of the hande.

Avoid contact with syste. If contact occurs, three thoroughly with water.

FLAMMABLE, KEEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR

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

OTHER INFORMATION Store below 110°F (43°C)
May decolor certain fabrice or surfa

BLACTIVE INGSEDIENTS Water, Propylone Glycol, Hydroxysthyl Celulase, Glycelin, tart-Bulyl Alcohol, Alco



- FDA Cleared ₱麽
- Sulfate-Free
- Paraben-Free
- BPA-Free







Visit us at care1 medical.ife 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

DRUG FACTS

ACTIVE INGREDIENT Ethyl Alcohol 72% viv......

roup reduce bacteria that potentially use disease. For use when scap and the are not weakable.

WARNINGS

For external was only, primarily on the abl of the hands.

Avoid contact with syes. If contact rines thoroughly with water.

PLANNABLE, KEEP AWAY FROM FIRE

STOP HER AND ASK A DOCTOR If mah or initiation or redness develops and lests

IGEP OUT OF REACH OF CHILDREN If product is sentioned, get medical help or context a Policer Control Center right sway.

OTHER INFORMATION Store below 110°F (43°C) May discolor certain fabrice or surfa

MACTIVE INCOMEDIENTS



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 |
| HYDRO XYPROPYL CELLULO SE (TYPE M) (UNII: U3JF9 1U133) | 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: V5VD430 YW9) | 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 Marketing Start Marketing End Item Code **Package Description** Date **Date** 1 NDC:78975-501- 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product 03/30/2020

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







Visit us at care1 medical.ife 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

DRUG FACTS

USES
To help reduce besteris that potentially commo disease. For use when some and water are not uvaliable.

WARNINGS For external use only, p of the hands.

Avoid contact with syste. If contact rince thoroughly with water.

FLASMABLE, KEEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR If mah or initiation or redness develo and lasts

NEEP OUT OF REACH OF CHILDREN If product in swellowed, get medical help or contact a Poleon Control Center right swey.

OTHER INFORMATION Store below 110°F (43°C) May discolor certain fabrice or su

MACTIVE INQUESTION



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: 3K9958 V | 90M) (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: V5VD430 YW9) | 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 | | |

| ı | 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 | |

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







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Fountain Valley, CA 92708
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Kills 99.99% Germs
Without Soap & Water
Advanced Gel
with Aloe Vera

NET 128 FLOZ [1 GAL] 3.78L

DRUG FACTS

Avoid contact with syes. If contact occurs, rince thoroughly with rester.

PLAMMABLE, KEEP AWAY PROB FIRE STOP HIS AND ASK A DOCTOR If nish or britistion or redness develops and limits

KEEP OUT OF REACH OF CHILDREN If product is swellowed, get medical help or contact a Poleon Control Center right swey.

OTHER INFORMATION Store below 110°F (43°C) May discolor certain fabrice or surface

BIACTIVE I HORBEDIENTE Water, Propylone Glycol, Hydroxysthyl Cellulase, Glycetin, terl-Bulyl Alcohol, Alas Vern, Fragminto.



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 | | | |
| | 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: V5VD430 YW9) | 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 | | |

| l | Packaging | | | |
|---|------------------|---|-------------------------|-----------------------|
| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:78975-503- | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| I | | | | |

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









DRUG FACTS

ACTIVE INGREDIENT Bthyl Alochol 72% v/v

USES

To help resizes besteris that potentially care cause decese. For use when soop and water are not available.

WARNINGS

For external use only, primarily on the eigh of this hands.

Avoid contact with eyes. If contact occurs, times theroughly with water.

FLAMMABLE, IGEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR.
If resh or inflation or redness developed inches

KEEP OUT OF REACH OF CHILDREN If product in mediawed, get reading help contact a Poleon Control Center right as

OTHER REPORDERATION Store below 110°F (45°C) May discolor sertain fabrics or surfaces

NACTIVE INGREDIENTS Water, Propylene Glycol, Hydrograftyl Callulose, Glycerin, heri-Bulyl Alachol, Aloc ин, Гиндинов.



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Kills 99.99% Germs Without Soap & Water

Advanced Gel with Aloe Vera



NET 33,8 FL OZ (1 L)

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

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

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

Ingredient Name Strength

| CYMBOPOGON CITRATUS LEAF (UNII: 06JMS448M5) | 0.5 mL in 100 mL |
|---|--------------------|
| COCONUT (UNII: 3RT3536 DHY) | 0.5 mL in 100 mL |
| ALOE (UNII: V5VD430 YW9) | 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 | | |

| ı | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | NDC:78975-504- 04 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |

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









DRUG FACTS

ACTIVE BIGREDIENT **PURPOSE**

USES

To help reduce besterie that potentially care cause disease. For use when soop and water are not available.

WARNINGS

For external use only, primarily on the extra of this hands.

Avoid contact with eyes. If contact occurs, times theroughly with water.

FLAMMABLE, KEEP AWAY FROM FIRE

STOP USE AND ASK A DOCTOR If resh or inflation or recinese develope and leefs

KEET OUT OF REACH OF CHILDREN If product in mediawed, get reading help or contact a Poleon Control Center right away.

OTHER REFORMATION Store below 110°F (43°C) May discolor sertain fabrics or surface

Water, Propriete Glycol, Hydrospettyl Cellulose, Glycerin, teri-Butyl Alechol, Aloe Vers, Fregrence.

PRODUCT INFO

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Distributed by: Care 1 Medical 11770 Warner Avenue #111 Fountain Valley, CA 92708 (949) 459-3645

Kills 99.99% Germs Without Soap & Water

Advanced Gel with Aloe Vera



NET 33,8 FL OZ (1 L)

| 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