

CARE1- 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.

Care 1 Hand Sanitizer - 1 gallon - 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 72% 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, hydroxypropyl cellulose, purified water USP, aloe, propanediol, lavender

Package Label - Principal Display Panel

• Sulfate-Free
• Paraben-Free
• BPA-Free

care 1
HAND SANITIZER
LAVENDER SCENTED

Made in the USA
72% Ethyl Alcohol

Kills 99.9% Germs Without Soap & Water
Advanced Gel with Aloe Vera
NET 128 FL OZ (1 GAL) 3.78L

Visit us at care1medical.life
Distributed by:
Care 1 Medical
11770 Warner Avenue #111
Fountain Valley, CA 92708
(949) 459-3645

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.	

NDC XXXXXXXX
8 60004 55797 5

3785 mL NDC: 78975-508-01

CARE1			
hand sanitizer gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78975-508
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
2-(1-CHLOROCYCLOPROPYL)-3-(2-CHLOROPHENYL)-1,2-PROPANEDIOL (UNII: SJ211700DZ)	80 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	10 mL in 100 mL
WATER (UNII: 059QF0K00R)	
ALOE (UNII: V5VD430YW9)	0.125 mL in 100 mL
LAVENDER OIL (UNII: ZBP1YXW0H8)	1 mL in 100 mL
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:78975-508-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

- Sulfate-Free
- Paraben-Free
- BPA-Free



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NDC XXXXXXXX



Marketing Information

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

Registrant - Care 1 (066368393)

Establishment

Name	Address	ID/FEI	Business Operations
Lauree LLC		102938225	manufacture(78975-508)

Revised: 12/2020

LAUREE LLC