

SIMPLISANITIZED- 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.

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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

Package Label - Principal Display Panel

Visit us at simplisanitized.com

designed to keep your family safe when you need it most...

Made in USA **Cruelty-free** **BPA Free**

Distributed by Lauree Labs
20512 Crescent Bay Drive #104
Lake Forest, CA 92630
Call us at (949) 446-9900

SimpliSanitized
Health & wellness straight from the manufacturer

Advanced Gel Hand Sanitizer with Aloe Vera

Made in USA with 72% Ethyl Alcohol

Kills most germs without soap or water

8 FL OZ (236.6 mL)

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	

250 mL NDC: 78975-581-81

Package label - Principal Display Panel

250 mL NDC: 78975-480-08

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FLAMMABLE, KEEP AWAY FROM FIRE

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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

SIMPLISANITIZED

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78975-480
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
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.125 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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78975-480-08	250 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	

SIMPLISANITIZED

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78975-581
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
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: 059QF0K00R)	
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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78975-581-81	250 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 - LAUREE LLC (102938225)

Establishment

Name	Address	ID/FEI	Business Operations
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LAUREE LLC		102938225	manufacture(78975-581, 78975-480)
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Revised: 6/2020

LAUREE LLC