

**CALILY HAND SANITIZER- alcohol gel**

**Calily Life Brands 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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**Calily Hand Sanitizer - Alcohol 80 %**

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**

<i>Active Ingredient</i>	<i>Purpose</i>
Alcohol 80% v/v.....	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 fire 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.

**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**

aminomethylpropanol, carbopol 940, FD&C Blue No. 1, fragrance, glycerin, hydrogen peroxide, water

**Questions or Comments?**

+1-732-994-4910 (M-F) 9 AM to 5 PM PST or [www.calilylife.com](http://www.calilylife.com)

**Package Label - Principal Display Panel**

50ml

NDC 74147-100-02

100ml

NDC 74147-100-04

500ml

NDC 74147-100-17



**Drug Facts**

Active ingredient	Purpose
Ethyl alcohol 80% w/v.....	Antiseptic

**Uses** Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**  
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**Directions**

- Place enough product to cover all surfaces. Rub hands together until dry.
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**Other information**

- store between 59-86°F (15-30°C) • avoid freezing and excessive heat above 40°C (104°F)

**TAMPER EVIDENT:** Do not use if clear seal over cap is broken or torn.

**Inactive ingredients** aminomethylpropanol, carbopol 940, FD&C Blue No. 1, fragrance, glycerin, hydrogen peroxide, water

**Questions or comments?** +1-732-994-4910 (M-F) 9 AM to 5 PM PST or www.calilylife.com

Distributed by:  
**Calily Life Brand LLC**  
Corona, CA 92882

## CALILY HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74147-100
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
CARBOMER 940 (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74147-100-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	
2	NDC:74147-100-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	
3	NDC:74147-100-17	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2020	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/16/2020	

**Labeler** - Calily Life Brands LLC (117455649)

Revised: 5/2020

Calily Life Brands LLC