

## **PRO-SANITIZE ADVANCED WITH ALOE VERA- hand sanitizer liquid**

### **Clean Beauty Concepts**

*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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The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, 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. (27.465%)
- e. Acrylates/C10 30 Alkyl acrylate crosspolymer(.20% v/v)
- f. Aminomethyl propanol (.06% v/v)
- g. Fragrance (Parfum) (.3% v/v)
- h. Aloe vera leaf extract (0.4%)

### **Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic

### **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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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

water(aqua), glycerin, acrylates/C10-30 alkyl acrylate crosspolymer, aminomethyl propanol, hydrogen peroxide, fragrance(parfum), Aloe Barbadensis

## Package Label - Principal Display Panel

473 mL NDC: 76665-004-16



**ADVANCED**  
**Hand Sanitizer**  
70%  
SULFATE FREE - PARABEN FREE

- HELPS KILL GERMS
- CONTAINS MOISTURIZER
- LEAVES HANDS SOFT

WITH ALOE VERA

e 473 mL | 1.6 fl oz



Kills most common germs that may make you sick.



LB670115-C6-20

Drug Fact	
<b>Active ingredient</b> Ethyl alcohol 70% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b> <b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keeps out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30° C (59-86° F). • Avoid freezing and excessive heat above 40° C (104° F).	
<b>Inactive ingredients</b> Water (aqua), glycerin, aloe barbadensis (aloe vera) leaf extract, acrylates/C10-30 alkyl acrylate crosspolymer, aminomethyl propanol, hydrogen peroxide, fragrance (parfum).	

Manufactured & Distributed By:  
**CLEAN BEAUTY CONCEPTS LLC**  
Gardena, CA 90248  
Info@cleanbeautyconcepts.com  
www.cleanbeautyconcepts.com

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1 95248 00050 6

60 mL NDC: 76665-004-02

Kills most common germs that may make you sick.

<b>Drug Fact</b>	
<b>Active ingredient</b> Ethyl alcohol 70% v/v. ....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>	
<b>When using this product</b> keeps out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• Store between 15-30°C (59-86°F).</li> <li>• Avoid freezing and excessive heat above 40°C (104°F).</li> </ul>	
<b>Inactive ingredients</b> Water (aqua), aloe barbadensis (aloe vera) leaf extract, acrylates/C10 30 alkyl acrylate crosspolymer, aminomethyl propanol, hydrogen peroxide, fragrance (parfum).	

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**ADVANCED**  
**Hand Sanitizer**



SULFATE FREE - PARABEN FREE

- HELPS KILL GERMS
- CONTAINS MOISTURIZER
- LEAVES HANDS SOFT



WITH ALOE VERA

e 60 ml | 2 fl oz

LB62011S-06-20

236 mL NDC: 76665-004-08



**ADVANCED**  
**Hand Sanitizer**



SULFATE FREE - PARABEN FREE

- HELPS KILL GERMS
- CONTAINS MOISTURIZER
- LEAVES HANDS SOFT



WITH ALOE VERA

e 236 ml | 8 fl oz

**ADVANCED**  
**Hand Sanitizer**

Kills most common germs that may make you sick.



LB58011S-06-20

<b>Drug Fact</b>	
<b>Active ingredient</b> Ethyl alcohol 70% v/v. ....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
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<b>Inactive ingredients</b> Water (aqua), aloe barbadensis (aloe vera) leaf extract, glycerin, acrylates/C10 30 alkyl acrylate crosspolymer, aminomethyl propanol, hydrogen peroxide, fragrance (parfum).	

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hand sanitizer liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76665-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.2 mL in 100 mL
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	27.465 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.4 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-004-16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/25/2020	
2	NDC:76665-004-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/25/2020	
3	NDC:76665-004-08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/25/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/25/2020	

**Labeler** - Clean Beauty Concepts (117491649)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Clean Beauty Concepts		117491649	manufacture(76665-004)