

**PROSANITIZE- benzalkonium chloride soap**  
**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 soap is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

- a. Benzalkonium chloride
- b. Water(aqua),
- c. sodium lauroyl sarcosinate,
- d. sodium cocoyl isethionate,
- e. cocamidopropyl betaine,
- f. cocamidopropyl
- g. PG-dimonium chloride phosphate,
- h. glycerin, polyquaternium-7,
- i. PEG-150 distearate,
- j. phenoxyethanol,
- k. sodium benzoate,
- l. citric acid,
- m. sodium chloride,
- n. tetrasodium EDTA,
- o. fragrance (parfum).

**Active Ingredient(s)**

Benzalkonium chloride 0.1% v/v. Purpose: Antibacterial

**Purpose**

Antibacterial

**Use**

Antibacterial soap to help reduce bacteria on skin that potentially can cause disease.

**Warnings**

For external use only. Flammable. Keep away from heat or flame.

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**

- Pump onto dry hands. Lather vigorously for at least 15 seconds, Rinse and dry thoroughly.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30°C (59-86°F) .
- Avoid freezing and excessive heat above 40°C (104°F).

## Inactive ingredients

Water(aqua), sodium lauroyl sarcosinate, sodium cocoyl isethionate, cocamidopropyl betaine, cocamidopropyl PG-dimonium chloride phosphate, glycerin, polyquaternium-7, PEG-150 distearate, phenoxyethanol, sodium benzoate, citric acid, sodium chloride, tetrasodium EDTA, fragrance (parfum).

## Package Label - Principal Display Panel

236 mL NDC: 76665-005-08

Antibacterial Soap-Pro Sanitize - 8oz Bottle - 07-13-2020



Label Specs: 4 color + White  
Coating: Laminate  
Material: White BOPP Adhesive  
Die: 6.3" x 4"

3785 mL NDC: 76665-005-01

**HOW TO USE ANTIBACTERIAL HAND SOAP**

APPLY HAND SOAP ON YOUR PALM

RUB HANDS TOGETHER FOR 15 SECONDS

RINSE WITH WARM WATER AND DRY THOROUGHLY

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Manufactured & Distributed By:  
**CLEAN BEAUTY CONCEPTS LLC**  
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 www.cleanbeautyconcepts.com

1 95248 00035 3

**Pro Sanitize**

**Antibacterial**

**HAND SOAP**

WITH MOISTURIZER

MADE IN THE USA

SULFATE FREE - PARABEN FREE

1 gallon | e3785ml

**ANTIBACTERIAL Hand Soap**

Kills most common germs that may make you sick.

LB360315-06-20

<b>Drug Fact</b>	<b>Purpose</b>
<b>Active ingredient</b> Benzalkonium chloride	Antibacterial
<b>Use(s)</b> Antibacterial soap to help reduce bacteria on skin that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. 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.	
<b>Directions</b> - Pump onto dry hands. Lather vigorously for at least 15 seconds. Rinse and dry thoroughly. - 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 (aqueal), sodium lauryl sarcosinate, sodium cocoyl isethionate, cocamidopropyl betaine, cocamidopropyl PG-dimonium chloride phosphate, glycerin, polyquatium-7, PEG-150 distearate, phenoxethanol, sodium benzoate, citric acid, sodium chloride, tetrasodium EDTA, fragrance (parfum).	

## PROSANITIZE

benzalkonium chloride soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76665-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 MW)</b> (UNII: 0L414VCS5Y)	0.4 mL in 100 mL
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.5 mL in 100 mL
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	0.2 mL in 100 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	0.5 mL in 100 mL
<b>FRAGRANCE LEMON ORC2001060</b> (UNII: K1725A7G95)	0.2 mL in 100 mL
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	5 mL in 100 mL
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	0.05 mL in 100 mL
<b>SODIUM LAUROYL SARCO SINATE</b> (UNII: 632GS99618)	9.25 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	0.3 mL in 100 mL
<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)	6.2 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	75.5 mL in 100 mL
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	0.1 mL in 100 mL
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)	0.5 mL in 100 mL
<b>COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE</b> (UNII: H2KVQ74JM4)	1.2 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:76665-005-08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/10/2020	
2	NDC:76665-005-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/10/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Clean Beauty Concepts		117491649	manufacture(76665-005)

Revised: 7/2020

Clean Beauty Concepts