# PRO-SANITIZE- 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.

-----

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.
- e. Acrylates/C10 30 Alkyl acrylate crosspolymer(.20% v/v)
- f. Aminomethyl propanol (.085% v/v)
- g. Fragrance (Parfum) (.50% v/v)

## 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.

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**

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

## **Package Label - Principal Display Panel**

60 mL NDC: 76665-002-02

Hand Sanitizer-Pro Sanitize - 2oz Bottle 70% Alcohol (Scented) - 04-27 -2020



170 mL NDC: 76665-002-06



236 mL NDC: 76665-002-08



3785 ML NDC: 76665-002-01



## **PRO-SANITIZE**

hand sanitizer liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76665-002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.2 mL in 100 mL		
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.5 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	27.64 mL in 100 mL		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.085 mL in 100 mL		

Packaging		
	Maybeting Staut	Maybeting End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-002- 06	178 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/22/2020	
2	NDC:76665-002- 02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/22/2020	
3	NDC:76665-002- 08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/22/2020	
4	NDC:76665-002- 01	$3785\ mL$ in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/22/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/22/2020		

## Labeler - Clean Beauty Concepts (117491649)

Establishment				
Name	Address	ID/FEI	Business Operations	
Clean Beauty Concepts		11749 1649	manufacture(76665-002)	

Revised: 4/2020 Clean Beauty Concepts