PRO-SANITIZE- benzalkonium chloride 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 sanitizer wipes is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

a. Benzalkonium Chloride (
b. Glycerol
c. Hydrogen peroxide
d. Sterile distilled water or boiled cold water.
e. Fragrance (Parfum)
f. Aloe vera leaf extract
g. Vitamin E

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

Use

Antiseptic wipes 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

- To dispense, lift cover, remove seal, pull center sheet from roll, twist to a point and feed through dispenser holde in cover. Keep lid closed to prevent moisture loss.
- Open and unfold wipe
- Thoroughly wipe hands, fingers and wrists. Be sure to use the entire wipe. Allow to dry.
- For dirty hands, use first wipe to clean hands, then discard wipe, sanitize with the second wipe.
- Discard after single use
- 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, hydrogen peroxide, fragrance(parfum), Aloe Barbadensis, Tocopheryl Acetate Vitamin E

Package Label - Principal Display Panel

80ct NDC: 76665-012

-80

PRO-SANITIZE

benzalkonium chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76665-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mL in 100 mL
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.5 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: 059QF0KO0R)	97.395 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-012-80	789 mL in 1 CANISTER; Type 0: Not a Combination Product	08/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/17/2020	

Labeler - Clean Beauty Concepts (117491649)

Establishment

Name	Address	ID/FEI	Business Operations
Clean Beauty Concepts		117491649	manufacture(76665-012)

Revised: 8/2020 Clean Beauty Concepts