

SAFETY FIRST- 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. aloe vera leaf extract.
- g. Eucalyptus Globulus, ext

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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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, aloe, Eucalyptus Oil

Package Label - Principal Display Panel

500 mL NDC: 76665-003-16

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%	Antiseptic

Clear Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

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

Do not use: On children less than 2 months of age • On open skin wounds • When using this product keep out of eyes, ears, mouth • In case of contact with eyes, rinse 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.

Manufactured by ParFramBoring, Pharmaceuticals

Directions: Place enough product on hands to cover all surfaces. Rub hands together until dry • Supervise children under age 6 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, aloe, acrylates/C10-30 alkyl acrylate crosspolymer, aminomethyl propanol, hydrogen peroxide, eucalyptus oil

* Kills 99.9% of most common germs NDC# 76665003



Kills 99.9% of Germs

16 FL. OZ. (500ml)

Drug Facts

Active Ingredient
Ethyl Alcohol 70%

Purpose
Antiseptic

Uses 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: On children less than 2 months of age • On open skin wounds • When using this product keep out of eyes, ears, mouth • In case of contact with eyes, rinse 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.

Distributed by ParFormulating Promotions®

SAFETY FIRST

Hand Sanitizer

WITH  ALOE

Kills 99.9% of Germs

8 FL. OZ. (240ml)

Directly
hands to
together i
under age
avoid swa

Other A
15-30C (f
excessive

Inactiva
Water
acrylates
crosspoly
hydrogen

* Kills 99.9%

NDC# 30X



Drug Facts

Active Ingredient

Ethyl Alcohol 70%

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: On children less than 2 months of age • On open skin wounds • When using this product keep out of eyes, ears, mouth • In case of contact with eyes, rinse 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.

Distributed by
FarFromBoring Promotions™



SAFETY FIRST

Hand Sanitizer

WITH  ALOE

Kills 99.9% of Germs

1 Gallon (128oz)

SAFETY FIRST

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76665-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	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)	0.3 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: 059QF0KO0R)	27.465 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06 mL in 100 mL
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	0.4 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-003-08	240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/14/2020	
2	NDC:76665-003-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/14/2020	
3	NDC:76665-003-16	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/14/2020	

Labeler - Clean Beauty Concepts (117491649)

Establishment

Name	Address	ID/FEI	Business Operations
Clean Beauty Concepts		117491649	manufacture(76665-003)

Revised: 6/2020

Clean Beauty Concepts