

SAFETY FIRST- alcohol 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. Alcohol (Isopropyl alcohol) (USP or Food Chemical Codex (FCC) grade) (75%, 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
- c. Hydrogen peroxide
- d. Sterile distilled water or boiled cold water. (27.465%)
- e. Fragrance (Parfum)
- f. Aloe vera leaf extract
- g. Tocopheryl Acetate (Vitamin E)
- h. Aminomethyl Propanol

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antibacterial

Use

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, 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.

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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 vera barbadensis (aloe vera) leaf extract, tocopheryl acetate (Vitamine E), hydrogen peroxide, Aminomethyl Propanol, fragrance(parfum)

Package Label - Principal Display Panel

3875 mL NDC: 76665-011-01

Hand Sanitizer-Safety First - 1 gallon | 70% IPA Alcohol Formula 10-05-202C

← 352.43 mm →

<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Isopropyl Alcohol 70%</td><td>Antibacterial</td></tr></tbody></table> <p>Uses Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame.</p> <p>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.</p> <p><small>Distributed by FairCombining Promotions*</small></p>	Active Ingredient	Purpose	Isopropyl Alcohol 70%	Antibacterial	<p>SAFETY™ FIRST Hand Sanitizer</p> <p><i>with Eucalyptus Leaf Vitamin E & Aloe</i></p> <p>Kills 99.9% of Germs*</p> <p>1 Gallon (3875ml)</p>	<p>Directions Place enough product on hands together until dry • Supervise children under age 6 when using this product to avoid swallowing</p> <p>Other Information Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F).</p> <p>Inactive Ingredients Water (aqua), glycerin, aloe vera barbadensis (aloe vera) leaf extract, tocopheryl acetate (vitamin E), aminomethyl propanol, eucalyptus leaf extract, fragrance (parfum)</p> <p>*Kills 99.9% of most common germs</p> <p> Manufactured in Gardena, CA 90248</p>
Active Ingredient	Purpose					
Isopropyl Alcohol 70%	Antibacterial					

Label
Coat
Material

473 mL NDC: 76665-011-16

Hand Sanitizer-Safety First - 16oz | 70% IPA Alcohol Formula 10-05-2020

Drug Facts	
Active Ingredient	Purpose
Isopropyl Alcohol 70%	Antibacterial
Uses 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.	
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 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive Ingredients Water (aqua), glycerin, aloe vera barbadensis (aloe vera) leaf extract, tocopheryl acetate (vitamin E), hydrogen peroxide, aminomethyl propanol, eucalyptus smithii myrtaceae (eucalyptus) oil.	

Distributed by FarFromBoring Promotions™



**SAFETY
FIRST**
Hand Sanitizer



*with Eucalyptus Leaf
Vitamin E & Aloe*

Kills 99.9% of Germs*

16 FL. OZ. (473ml)



Manufactured in
Gardena, CA 90248

NCD#: 76665-011-16



0 20160 12010 3

Label Specs: 4 color + White
Coating: Laminate
Material: Clear BOPP Adhesive
Die Line: 7.3 x 5.5

236mL NDC: 76665-011-08

Hand Sanitizer-Safety First - 8oz | 70% IPA Alcohol Formula 10-05-2020

<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Isopropyl Alcohol 70%</td> <td>Antibacterial</td> </tr> </table> <p>Uses Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame.</p> <p>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.</p> <p><small>Distributed by FairFromBoring Promotions®</small></p>	Active Ingredient	Purpose	Isopropyl Alcohol 70%	Antibacterial	<p>SAFETY FIRST Hand Sanitizer</p> <p>with Eucalyptus Leaf Vitamin E & Aloe</p> <p>Kills 99.9% of Germs*</p> <p>8 FL. OZ. (236ml)</p>	<p>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.</p> <p>Other Information Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive Ingredients Water (aqua), glycerin, aloe vera barbadensis (aloe vera) leaf extract, tocopheryl acetate (vitamin E), hydrogen peroxide, aminomethyl propanol, eucalyptus smithii myrtaceae (eucalyptus) oil.</p> <p><small>*Kills 99.9% of most common germs</small></p> <p>NDC#: 76665-011-08</p> <p>Manufactured in Gardena, CA 90248</p> <p>0 20800 36010 4</p>
Active Ingredient	Purpose					
Isopropyl Alcohol 70%	Antibacterial					

Label Specs: 4 color + White
Coating: Laminate
Material: Clear BOPP Adhesive
Die Line: 6 x 4

SAFETY FIRST

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76665-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS SMITHII OIL (UNII: X4023CB3OK)	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

CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	0.2 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.665 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-011-01	3875 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/17/2020	
2	NDC:76665-011-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/17/2020	
3	NDC:76665-011-08	236 mL in 1 BOTTLE, PUMP; 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(76665-011)

Revised: 10/2020

Clean Beauty Concepts