HAND SANITIZER- alcohol gel Tropical Green Organics

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 in the preparation of the product (percentage in final product formulation)

- 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
- c. TRIETHANOLAMINE BENZOATE
- d. Aloe Vera leaf
- e. CARBOMER
- f. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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

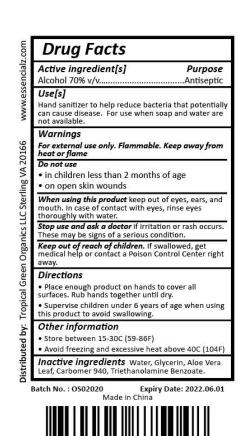
Water Glycerol Aloe Vera leaf Carbomer TRIETHANOLAMINE BENZOATE

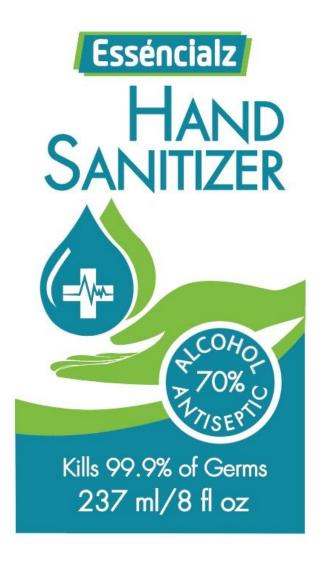
Package Label - Principal Display Panel

60 ML NDC: 76914-222-01



237 ml: NDC: 76914-222-02





500 ml: NDC: 76914-222-03

Drug Facts

Active ingredient[s]

Alcohol 70% v/v.....

Purpose Antiseptic

Use[s]

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Inactive ingredients Water, Glycerol, Aloe Barbadensis leaf juice, Carbomer, Triethanolamine

Batch No.: OS02020 Expiry Date: 2022.06.01 Made in China





Drug Facts Active ingredient[s] Purpose Alcohol 70% v/v... Use[s] 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. 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, Glycerin, Aloe Vera Leaf, Carbomer 940, Triethanolamine Benzoate.

Batch No.: 0S02020 Expiry Date: 2022.06.01

Made in China

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HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76914-222

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			
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
TRIETHANO LAMINE BENZO ATE (UNII: M3EN4GC19W)				
CARBOMER 940 (UNII: 4Q93RCW27E)				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:76914-222-02	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2020			
2	NDC:76914-222-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2020			
3	NDC:76914-222-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2020			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/09/2020			

Labeler - Tropical Green Organics (020059251)

Revised: 5/2020 Tropical Green Organics