

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

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
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Other information	
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Inactive ingredients Water, Glycerin, Aloe Vera Leaf, Carbomer 940, Triethanolamine Benzoate.	

Distributed by: Tropical Green Organics LLC Sterling VA 20166
www.essentialz.com

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





500 ml : NDC: 76914-222-03

Distributed by: Tropical Green Organics LLC Sterling VA 20166 www.essentialz.com

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 70% v/v.....	Antiseptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<i>For external use only. Flammable. Keep away from heat or flame</i>	
Do not use	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Water, Glycerol, Aloe Barbadosis leaf juice, Carbomer, Triethanolamine.	

Batch No. : OS02020 Expiry Date: 2022.06.01

Made in China





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



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: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHANOLAMINE BENZOATE (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