#### ON THE GO- alcohol liquid Eco Cups International Corp

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.

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#### Hand saniter Ethyl Alcohol 80%

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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.

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 80% 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**

glycerin, hydrogen peroxide, purified water USP

#### Package Label - Principal Display Panel



ON THE GO			
alcohol liquid			
Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:77675-100(NDC:76710-984)

Route	of	Administration	
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A	ctive Ingredien	t/Active Moiety				
		Ingredien	t Name		<b>Basis of Strength</b>	Strength
A	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	80 mL in 100 mL	
_						
1	nactive Ingredie					
Ingredient Name			Strength			
	GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL		
WATER (UNII: 059QF0KO0R)						
P	roduct Charact	eristics				
С	olor			Score		
S	hape			Size		
F	avor			Imprint Code		
С	ontains					
P	ackaging					
#	Item Code	Package Description		Marketing Start Date	Marketing End Date	
1	NDC:77675-100-01	1.35 mL in 1 POUCH; Type 0: Not a Combination Product		06/26/2020		

## Decrease bacteria on the skin that could cause disease



NDC: 77675-100-01

Made in the USA

# Drug Facts Purpose : Antiseptic

Active Ingredient: Ethyl alcohol 80% v/v Inactive ingredients: water, glycerin, colorants Warnings : For external use, hands only Flammable: Keep away from heat and flame When using the product : keep out of eyes. Keep out of reach of children Directions: wet hands thoroughly with product and allow to dry without wiping. Other Information: do not store above105°F

Marketing Inform	mation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/25/2020	

Labeler - Eco Cups International Corp (095605399)

Registrant - Eco Cups International Corp (095605399)

### Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Eco Cups International Corp		095605399	repack(77675-100)

Revised: 6/2020

Eco Cups International Corp