#### HAND SANITIZER- alcohol solution Ecom Food Industries Corporation

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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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

#### 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.

## 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.

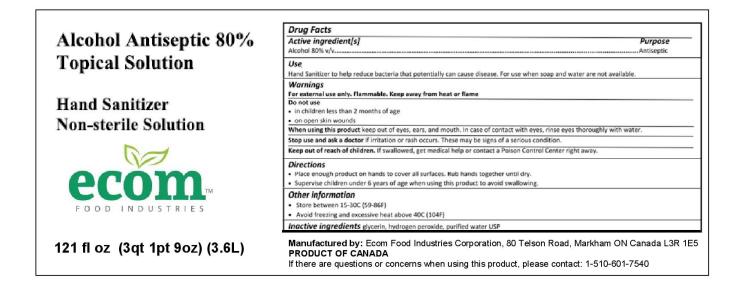
#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel



IAND SANITIZER				
lcohol solution				
Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (So	ource)	NDC:75790-001
Route of Administration	TOPICAL			
Active Ingredient/Active	Moiety			
In	H	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M)	ALCOHOL		80 mL in 100 mL	
Inactive Ingredients				
0			Strength	
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100	1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: B		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				

Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:75790-001-33	1000 mL in 1 JUG; Type 0: Not a Combination Product	04/24/2020					
<b>2</b> NDC:75790-001-36	3600 mL in 1 JUG; Type 0: Not a Combination Product	04/24/2020					
Marketing Information							
Marketing Inf	ormation						
Marketing Info Marketing Categor		Marketing Start Date	Marketing End Date				
	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				

Labeler - Ecom Food Industries Corporation (243547028)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Ecom Food Industries Corporation		243547028	manufacture(75790-001)

Revised: 4/2020

Ecom Food Industries Corporation