## HAND SANITIZER- ethyl alcohol 70% gel Sun Hing Foods Inc

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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# LORO HAND SANITIZER Anti-Bacterial Gel ETHYL ALCOHOL 70%

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)

Ethyl Alcohol 70%, Isopropyl Alcohol 0.5%. Purpose: Antiseptic

#### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria on the skin.

#### **Warnings**

For external use only. Flammable. Keep away from fire or flame

#### Do not use

• Children under 6 years of age should be supervised when using LORO

#### When using this product

do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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 appears and lasts.

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 below 110 Degree F (43 Degree C)
- May discolor certain fabrics or surfaces

# Manufacture By:

Hanoi Biology Chemistry Group Corporation 252/57 Tay Son, Trung Liet Ward, Dong Da District Hanoi, Vietnam

## **Inactive ingredients**

Water (Aqua), Acrylite Crosspolymer, Glycerin, Ginger Oil.

#### **Package Label - Principal Display Panel**

Sticker size: 118 x 86 mm



474 mL NDC: 78185-002-01

#### HAND SANITIZER

ethyl alcohol 70% gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78185-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:78185-002- 01	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Sticker size: 118 x 86 mm



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

# Labeler - Sun Hing Foods Inc (066460726)

Revised: 3/2020 Sun Hing Foods Inc