

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.

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 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 111 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Sticker size: 570 x 168 mm



5000 mL NDC: 78185-004-01

HAND SANITIZER

ethyl alcohol 70% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 185-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78185-004-01	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Sticker size: 570 x 168 mm



Marketing Information

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

