LORO 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%
30 FL OZ (888mL)

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) (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. Isopropyl Alcohol (0.2% v/v).
- c. Glycerol (0.25% v/v).
- d. Acrylite Crosspolymer (0.5% v/v).
- e. Ginger Oil (0.25% v/v)/
- f. Water (29% v/v).

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% v/v, Isopropyl Alcohol 0.5% v/v. 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 heat or flame

Do not use

- Children under 6 years of age should be supervised when using LORO
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When using this product do not use in or near the eyes. In case of contact, 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.

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Directions

- Place enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using LORO.

Other information

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

Inactive ingredients

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

Package Label - Principal Display Panel



888 mL NDC: 78185-012-01

LORO HAND SANITIZER

ethyl alcohol 70% gel

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78185-012 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------|---------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 0.2 mL in 888 mL | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 888 mL | |

| Inactive Ingredients | | | |
|---|------------------|--|--|
| Ingredient Name | Strength | | |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) | 0.5 mL in 888 mL | | |

| GLYCERIN (UNII: PDC6A3C0OX) | 0.25 mL in 888 mL |
|--------------------------------|-------------------|
| WATER (UNII: 059QF0KO0R) | 29 mL in 888 mL |
| GINGER O IL (UNII: SAS9Z1SVUK) | 0.05 mL in 888 mL |

| Product Characteristics | | | |
|-------------------------|--------------|--|--|
| Color | Score | | |
| Shape | Size | | |
| Flavor | Imprint Code | | |
| Contains | | | |

| ı | Packaging | | | | |
|---|-----------|-----------------|---|-----------------------------|--------------------|
| ı | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 N | DC:78185-012-01 | 888 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |

Sticker size: 164.6 x 120 mm



| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 03/30/2020 | |
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Labeler - Sun Hing Foods Inc (066460726)

Revised: 3/2020 Sun Hing Foods Inc