

HAND SANITIZER- isopropyl alcohol gel
GUILIN LIFENG MEDICAL SUPPLIES CO.,LTD.

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.

Hand Sanitizer Gel

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. Ethyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin (1.45% v/v).
- c. Moisture Complex.
- d. Herbal Essence (0.125% v/v).
- e. Carbopol
- f. Fragrance

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 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to decrease bacteria on the skin that may cause disease.

Warnings

For external use only: hands or skin surface

Flammable, keep away from fire or flame

Caution for those who are allergic to alcohol

Do not use

- For infants or young children (under 6) without supervision
- When you are allergic to alcohol

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

- Wet hands thoroughly with product and allow to dry without wiping.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

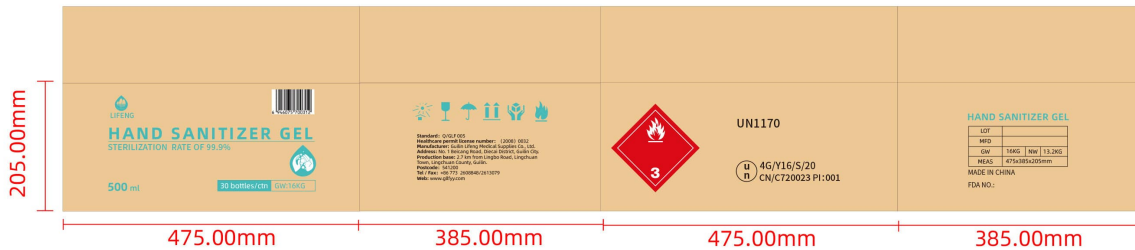
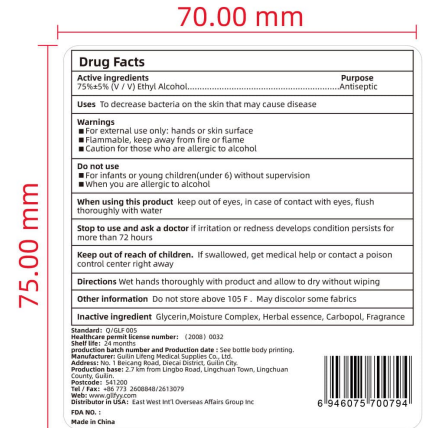
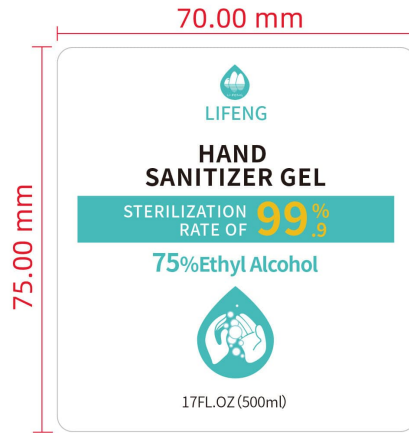
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, Moisture Complex, Herbal Essence, Carbopol, Fragrance

Package Label - Principal Display Panel

17FL.OZ (500ml)



500 ml NDC: 81898-102-11

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81898-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3COOX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

WATER (UNII: 059QF0KO0R)

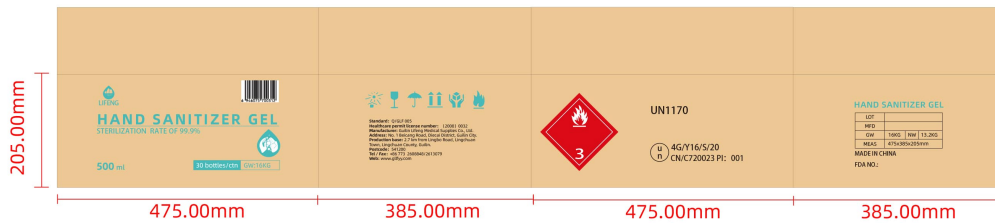
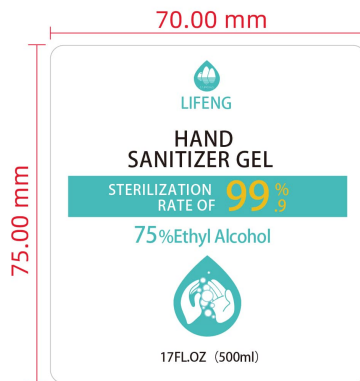
Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81898-102-10	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

17FL.OZ (500ml)



Marketing Information

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

Labeler - GUILIN LIFENG MEDICAL SUPPLIES CO.,LTD. (546406728)

Registrant - GUILIN LIFENG MEDICAL SUPPLIES CO.,LTD. (546406728)

Establishment

Name	Address	ID/FEI	Business Operations
GUILIN LIFENG MEDICAL SUPPLIES CO.,LTD.		546406728	manufacture(81898-102)

Revised: 5/2021

GUILIN LIFENG MEDICAL SUPPLIES CO.,LTD.