

LUOYS HAND SANITIZER- alcohol gel
ZheJiang Yiwu Limei Cosmetics 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.

NA

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease

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.

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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

purified water, glycerin, propylene glycol, carbomer, triethanolamine

Package Label - Principal Display Panel

29 mL NDC: 74765-004-01

50mL NDC: 74765-004-02



60 mL NDC: 74765-004-03

100 mL NDC: 74765-004-04

300 mL NDC: 74765-004-05

500 mL NDC: 74765-004-06

1000 mL NDC: 74765-004-07

2000 mL NDC: 74765-004-08

3000 mL NDC: 74765-004-09

5000 mL NDC: 74765-004-10

80 mL NDC: 74765-004-11

236mL NDC:74465-004-12

LUOYS HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74765-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 980 (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74765-004-01	29 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
2	NDC:74765-004-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
3	NDC:74765-004-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
4	NDC:74765-004-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
5	NDC:74765-004-05	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
6	NDC:74765-004-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
7	NDC:74765-004-07	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
8	NDC:74765-004-08	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
9	NDC:74765-004-	3000 mL in 1 BOTTLE; Type 0: Not a Combination	04/26/2020	

09	Product	04/20/2020	
10	NDC:74765-004-10 5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	
11	NDC:74765-004-11 80 mL in 1 TUBE; Type 0: Not a Combination Product	03/20/2020	
12	NDC:74765-004-12 236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/20/2020	

Labeler - ZheJiang Yiwu Limei Cosmetics Co., Ltd (679892245)

Establishment

Name	Address	ID/FEI	Business Operations
ZheJiang Yiwu Limei Cosmetics Co.,Ltd		679892245	manufacture(74765-004)

Revised: 4/2020

ZheJiang Yiwu Limei Cosmetics Co., Ltd