# ANTI BACTERIAL HAND SANITIZER- alcohol liquid Leads (China) Biotechnology 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.

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#### Anti bacterial Hand Sanitizer

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)**

Alcohol 70%-75% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **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**

glycerin, hydrogen peroxide, purified water USP

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



### **Anti bacterial Hand Sanitizer**

**Drug Facts** 

Active ingredient Alcohol 70% v/v..... Antiseptic

Purpose

\*Kills 99.9% of Germs. Proven effective against germs, including: Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae.

Directions for use: Squeeze thumbnail size amount your palm rub hands until dry. Store below 30°C

INDREDIENTS:

ALCOHOL, WATER (AQUA), GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM), ALOE BARBADENSIS LEAF EXTRACT.

**Caution: Highly Flammable**. Keep away from fire or flame and children.In case of eye contact, flush with water Discontinue useif skin irritaion occurs. If condition persists or swallowed, consult a doctor.

Manufactured By:

(China) Leads (China) Biotechnology Co., Ltd No.198 Yintai East Road, Changtai Country, Zhangzhou

City Fujian Province China

0.1fl oz / 3ml



### ADVANCE BEAUTY INTERNATIONAL COMPANY

Sales: Title: LX-OEM-200003
30ml Hand Sanitizer
Bottle Front & Back Label

Job. No.:
Rev.:
0
Date:
Prepared by:
Page: 1 of 1

Size:	26 x 43m	m	Printing Sp	ecification:
Material:	80g White	e PE Label	Diecut	M CMYK
Finishing /	Costing:	Gloss Varnishing		





Front

Back

Internal use only

Prepared by	Checked by	Approved by (Sales)	Approved by (R&D)		
				Client's Confirmation:	
					Company Chop & Signature
				Date:	. ,



#### **Anti bacterial Hand Sanitizer**

Drug Facts Active ingredient

Purpose

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Manufactured By: (China) Leads (China) Biotechnology Co., Ltd No. 198 Yintai East Road, Changtai Country, Zhangzhou City' Fujian Province China'

Made in China 3.4fl oz / 100ml

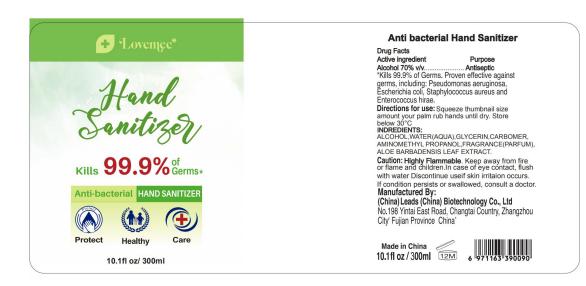




#### ADVANCE BEAUTY INTERNATIONAL COMPANY

 Sales:
 Title: LX-0EM-200001
 Job. No.: Rev.: 2 Date: 2020.03.28
 LX-0EM-200001 Propage by: Christy Prepared by: Christy Page: 1 of 1

Size:	160x75mm		Printing Sp	ecification:
Material:	80g White	PE Label	Diecut	M CMYK
Finishing /	Costing:	Gloss Varnishing		



Internal use only

Prepared by	Checked by	Approved by (Sales)	Approved by (R&D)		
				Client's Confirmation:	
					Company Chop & Signature
				Date:	

#### ADVANCE BEAUTY INTERNATIONAL COMPANY

Job. No.: Rev.: Date: Title: LX-0EM-200002 Clients: Prepared by: Christy Page: 1 of 1

2011-Anti-bacterial

Size:	60 x 104r	nm	Printing Sp	ecification:
Material:	80g White	e PE Label	Diecut	M CMYK
Finishing /	Costing:	Gloss Varnishing		





Company Chop & Signature

LX-0EM-200002

Internal use only				
Prepared by	Checked by	Approved by (Sales)	Approved by (R&D)	
				Client's Confirmation
				Date:

800 mL NDC: 77969-001-07



#### **Anti bacterial Hand Sanitizer**

**Drug Facts** 

Active ingredient **Purpose** Alcohol 70% v/v..... .. Antiseptic

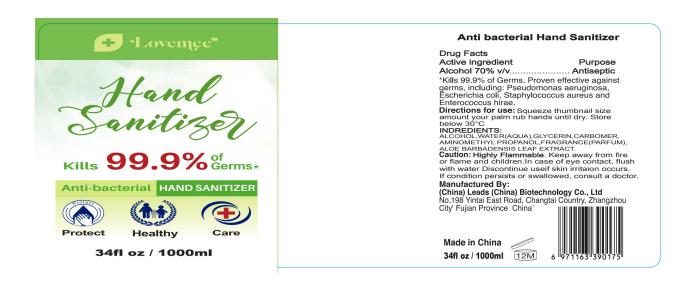
\*Kills 99.9% of Germs. Proven effective against germs, including: Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae.

**Directions for use:** Squeeze thumbnail size amount your palm rub hands until dry. Store below 30°C

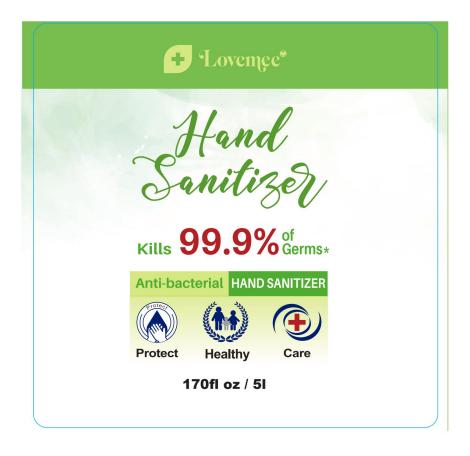
INDREDIENTS:
ALCOHOL, WATER(AQUA), GLYCERIN, CARBOMER,
AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM).







5000 mL(5L) NDC: 77969-001-09



#### **Anti bacterial Hand Sanitizer**

**Drug Facts** 

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INDREDIENTS: ALCOHOL, WATER(AQUA), GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM),

ALOE BARBADENSIS LEAF EXTRACT.

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Manufactured By:

(China) Leads (China) Biotechnology Co., Ltd No.198 Yintai East Road, Changtai Country, Zhangzhou City' Fujian Province China'

Made in China

170fl oz / 5l



### ANTI BACTERIAL HAND SANITIZER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77969-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 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)					

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:77969-001-01	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
2	NDC:77969-001-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
3	NDC:77969-001-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
4	NDC:77969-001-05	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
5	NDC:77969-001- 06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
6	NDC:77969-001-07	800 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
7	NDC:77969-001- 08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			
8	NDC:77969-001- 09	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/20/2020		

# Labeler - Leads (China) Biotechnology Co., Ltd. (416037073)

# **Registrant** - Leads (China) Biotechnology Co., Ltd. (416037073)

Establishment					
Name	Address	ID/FEI	Business Operations		
Leads (China) Biotechnology Co., Ltd.		416037073	manufacture(77969-001)		

Revised: 9/2020 Leads (China) Biotechnology Co., Ltd.