

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.

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.

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.

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

3 mL NDC: 77969-001-01



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), ALOE BARBADENSIS LEAF EXTRACT.

Caution: Highly Flammable. Keep away from fire or flame and children. In case of eye contact, flush with water. Discontinue use if skin irritation 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 43mm	Printing Specification:
Material:	80g White PE Label	<input type="checkbox"/> Diecut <input checked="" type="checkbox"/> 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:

100 mL NDC: 77969-001-04



Anti bacterial Hand Sanitizer

Drug Facts

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

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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 use if skin irritation 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

Made in China
3.4fl oz / 100ml



300 mL NDC: 77969-001-05

ADVANCE BEAUTY INTERNATIONAL COMPANY

Sales: Title: LX-OEM-200001
 Clients:
 2011-Anti-bacterial

Job. No.: LX-OEM-200001
 Rev.: 2
 Date: 2020.03.28
 Prepared by: Christy
 Page: 1 of 1

Size:	160x75mm	Printing Specification:
Material:	80g White PE Label	<input type="checkbox"/> Diecut <input checked="" type="checkbox"/> CMYK
Finishing / Costing:	Gloss Varnishing	



The label features a green header with the 'Lovençe' logo. The main text reads 'Hand Sanitizer' in a large, elegant script. Below this, it states 'Kills 99.9% of Germs*'. A green banner highlights 'Anti-bacterial HAND SANITIZER'. At the bottom, there are three icons: a hand being washed (Protect), a family (Healthy), and a medical cross (Care). The volume '10.1 fl oz / 300ml' is printed at the very bottom.

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), ALOE BARBADENSIS LEAF EXTRACT.

Caution: Highly Flammable. Keep away from fire or flame and children. In case of eye contact, flush with water. Discontinue use if skin irritation 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

Made in China  
 10.1 fl oz / 300ml 6 971163 390090

Internal use only

Prepared by	Checked by	Approved by (Sales)	Approved by (R&D)

Client's Confirmation: _____
 Date: _____ Company Chop & Signature

500 mL NDC: 77969-001-06

ADVANCE BEAUTY INTERNATIONAL COMPANY

Sales: Title: LX-OEM-200002
 Clients: 2011-Anti-bacterial

Job. No.: LX-OEM-200002
 Rev: 2
 Date:
 Prepared by: Christy
 Page: 1 of 1

Size:	60 x 104mm	Printing Specification:
Material:	80g White PE Label	<input type="checkbox"/> Diecut <input checked="" type="checkbox"/> CMYK
Finishing / Costing:	Gloss Varnishing	



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), ALOE BARBADENSIS LEAF EXTRACT.

Caution: Highly Flammable. Keep away from fire or flame and children. In case of eye contact, flush with water. Discontinue use if skin irritation 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

Made in China
 16.9fl oz / 500ml  

Internal use only

Prepared by	Checked by	Approved by (Sales)	Approved by (R&D)

Client's Confirmation: _____
 Date: _____
 Company Chop & Signature

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).

Kills **99.9%** of Germs*

Anti-bacterial HAND SANITIZER



Protect



Healthy



Care

27fl oz / 800ml

ALOE BARBADENSIS LEAF EXTRACT.

Caution: Highly Flammable. Keep away from fire or flame and children. In case of eye contact, flush with water. Discontinue use if skin irritation 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

Made in China

27fl oz / 800ml



6 971163 390151



1000 mL NDC: 77969-001-08

 Lovence®

Hand Sanitizer

Kills **99.9%** of Germs*

Anti-bacterial HAND SANITIZER

  

Protect Healthy Care

34fl oz / 1000ml

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), ALOE BARBADENSIS LEAF EXTRACT.

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

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

Made in China

34fl oz / 1000ml



6 971163 390175

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

 Lovence®

Hand Sanitizer

Kills **99.9%** of Germs*

Anti-bacterial HAND SANITIZER

  

Protect Healthy Care

170fl oz / 5l

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), ALOE BARBADENSIS LEAF EXTRACT.

Caution: Highly Flammable. Keep away from fire or flame and children. In case of eye contact, flush with water. Discontinue use if skin irritation 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

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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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.