

HAND SANITIZER- ethyl 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.

Hand Sanitizer Spray

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. Isopropyl 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. 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)

Ethyl 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

Water(aqua), parfum(fragrance)

Package Label - Principal Display Panel

15 ml NDC: 77969-003-01



Hand Sanitizer Spray - 75% Alcohol Formula

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

Directions for use: Hold spray 15-20cm from surface. Spray pre-cleaned surface 2 to 3 seconds until covered with mist. Allow to stand 10 minutes to air dry. Repeat applications as necessary.

INDREDIENTS:

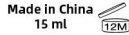
75% Ethyl Alcohol, WATER(AQUA), PARFUM (FRAGRANCE), CI 17200, CI 42090

Caution: Highly Flammable. Keep away from fire of 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.



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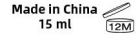
75% Ethyl Alcohol, WATER(AQUA), PARFUM (FRAGRANCE), CI 19140, CI 42090

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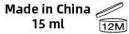
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INDREDIENTS:

75% Ethyl Alcohol, WATER(AQUA), PARFUM (FRAGRANCE), CI 14700

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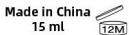
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HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77969-003

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
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77969-003-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

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(77969-003)

Revised: 6/2020

Leads (China) Biotechnology Co., Ltd.