

HAND SANITIZER- alcohol gel
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

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:

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.

Glycerol (1.45% v/v).

Hydrogen peroxide (0.125% v/v).

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 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.

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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.

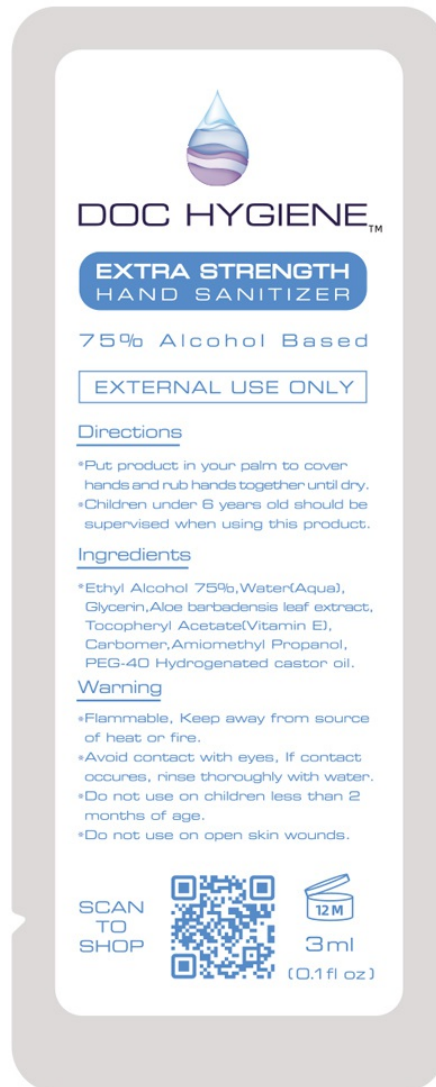
Other information

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

water(aqua), glycerin, carbomer, aminomethyl propanol, aloe leaf extract, PEG-40 hydrogenated castor oil, tocopheryl acetate

3 mL NDC: 77969-002-01



DOC HYGIENE™
HAND SANITIZER
EXTRA STRENGTH
GERM KILLING POWER



Kills Up To
99.9%
Of Germs

3 ml



DOC HYGIENE™
EXTRA STRENGTH
HAND SANITIZER

Drug Facts

Active ingredients	Purpose
• Ethyl Alcohol 75% v/v.....	Antiseptic

Uses

- For use when antibacterial soap and water are not available.
- Hand Sanitizer to help reduce illness causing bacteria on the skin.

Warnings

- **Flammable. Keep away from sources of heat or flame.**
- **For external use only.**
- **When using this product,** keep out of or away from eyes, ears, nose and mouth. In case of contact, rinse thoroughly with water.
- **Stop use and ask a doctor** if rash or irritation occurs as these may be signs of a serious condition.
- **Keep out of reach of children.** If swallowed, seek medical help or contact a Poison Control Center immediately.

Directions

- Open packet. Lightly squeeze the packet into the palm of your hand with enough product to cover both of your hands. Rub hands together, spread product over the backs of each hand, and in between each finger.
- Children under 6 years of age should be supervised when using this product.

Other information

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

Inactive ingredients

- Water(Aqua), Glycerin, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate(VitaminE), Carbomer, Aminomethyl Propanol, PEG-40 Hydrogenated Castor Oil.





30 mL NDC: 77969-002-02

HAND SANITIZER

75% ALCOHOL
BASED

SAMPLE

30 ml

Manufactured By:

Leads (China) Biotechnology Co.,Ltd

No.198 Yintai East Road,Changtai Country,Zhangzhou
City,Fujian Province,China.

Front Label

EXTRA STRENGTH
HAND SANITIZER

75% Alcohol Based

EXTERNAL USE ONLY

Directions

Put product in your palm to cover hands and rub hands together until dry.

Children under 6 years old should be supervised when using this product.

Ingredients

Ethyl Alcohol 75%, Water(Aqua), Glycerin,Aloe barbadensis leaf extract, Vitamin E,Carbomer,Aminomethyl Propanol,Hydrogenated castor oil

Warning

Flammable,Keep away from source of heat or fire.

Avoid contact with eyes, If contact occurs,rinse thoroughly with water.

Do not use on children less than 2 months of age.

Do not use on open skin wounds.

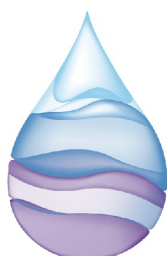
MADE IN CHINA



Back Label

300 mL NDC: 77969-002-03

DOC HYGIENE™
HAND SANITIZER
EXTRA STRENGTH
GERM KILLING POWER



Kills Up To
99.9%
Of Germs

300 ML
(10.15 fl.oz)



DOC HYGIENE™

Drug Facts	
Active Ingredients	Purpose
•Ethyl Alcohol 75% V/V	Antiseptic
Uses	
•For use when antibacterial soap and water are not available.	
•Hand Sanitizer to help reduce illness causing bacteria on the skin.	
Warnings	
•Flammable, Keep away from sources of heat or flame.	
•For external use only.	
•When using this product, keep out of or away from eyes, ears, nose and mouth. In case of contact, rinse thoroughly with water.	
•Stop use and ask a doctor if rash or irritation occurs as these may be signs of a serious condition.	
•Keep out of reach of children. If swallowed, seek medical help or contact a Poison Control Center immediately.	
Directions	
•Open packet. Lightly squeeze the packet into the palm of your hand with enough product to cover both of your hands. Rub hands together,spread product over the back of each hand, and in between each finger.	
•Children under 6 years of age should be supervised when using this product.	
Other information	
•Store between 59-86°F (15-30°C)	
•Avoid freezing. Avoid excessive heat above 104°F (40°C)	
Inactive Ingredients	
•Water(Aqua), Glycerin, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate (Vitamin E), Carbomer, Aminomethyl Propanol, PEG-40 Hydrogenated Castor Oil.	



Distributed in the USA by DOC HYGIENE www.DocHygiene.com
Question or Comments? info@DocHygiene.com

HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77969-002	
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)		0.5 mL in 100 mL		
WATER (UNII: 059QF0KO0R)		22.09 mL in 100 mL		
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)		0.25 mL in 100 mL		
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)		0.05 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)		0.5 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		0.1 mL in 100 mL		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		0.01 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77969-002-01	3 mL in 1 PACKET; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77969-002-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	06/01/2020	

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(77969-002)