

HAND SANITIZER- 75% alcohol liquid
Jiangsu Doer 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 55449-075-01 500ml 55449-075-02 946ml

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)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

USE: for disinfection, sterilization. relief of prockly heat. insect bites, hygenic purposes and general antiseptic.

Warnings

For external use only. if taken internally serious gasric disturbances will result.

Flammable. Keep away from heat or flame. Use only in a well-ventilated area; fumes may be toxic.

Do not use

- in children less than 2 months of age

- on open skin wounds

do not get into eyes.

do not apply over large areas of the body.

do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if condition persists or gets worse. Keep out reach of children.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions:

- clean affected area.
- apply small amount of this product on the area 1-3 times daily.
- if bandaged let dry first.
- may be covered with a sterile bandage.

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

946 ml NDC:55449-075-01



+
75% ALCOHOL






LIQUID • DISINFECTANT ALCOHOL

- First Aid Antiseptic
- Anti-Bacterial Efficiency 99.99%

WARNING FLAMMABLE  Keep away from heat, spark, electrical, fire or flame

Use only in a well-ventilated area
Fumes may be harmful

32 FL OZ - 946 ML

Drug Facts	
Active ingredient: 75% Ethyl Alcohol	Purpose Antiseptic
Inactive ingredient: Glycerol, Hydrogen peroxide, Sterile distilled water	
USE: for disinfection, sterilization, relief of prickly heat, insect bites, hygienic purposes, and general antiseptic	
Warnings For external use only,	
<ul style="list-style-type: none"> • if taken internally, serious gastric disturbances will result <p>Flammable, keep away from fire or flame.</p> <ul style="list-style-type: none"> • Use only in a well-ventilated area; fumes may be toxic 	
Ask a doctor before use if you have deep or puncture wounds, animal bites, or serious burns.	
When using this product	
<ul style="list-style-type: none"> • do not get into eyes • do not apply over large areas of the body • do not use longer than one week unless directed by a doctor 	
Stop use and ask a doctor if condition persists or gets worse. Keep out reach of children	
Directions	
<ul style="list-style-type: none"> • clean affected area • apply small amount of this product on the area 1-3 times daily • if bandaged, let dry first • may be covered with a sterile bandage 	
Other information	
<ul style="list-style-type: none"> • store at room temperature • does not contain, nor is intended as a substitute for grain or ethyl alcohol 	
The Device Production License: Jiangsu Commission of Health Lincense Production License #(2020)3213-0004 with Producdtion at Jiangsu Doer biotechnology Co., Ltd / No.170, Group6, Zhuangxi, Village, Yanghe Town, Yanghe, New District, Suqian, Jiangsu 223800, China (CHN)	
Producer Made in GUAM for 4D WHOLESale At 275 FARENHOLT AVENUE STE G PMB 164 TAMUNING, GUAM 96913	
 6 1973245 1180179	    3 years

HAND SANITIZER

75% alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55449-946
Route of Administration	EXTRACORPOREAL		

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
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55449-946-01	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/29/2021	

Labeler - Jiangsu Doer biotechnology Co., Ltd (554529820)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Doer biotechnology Co., Ltd		554529820	manufacture(55449-946)

Revised: 10/2021

Jiangsu Doer biotechnology Co., Ltd