

DISINFECTANT HAND SANITIZER- isopropyl alcohol gel
Guangzhou Jiuke Fine Chemical 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.

Disinfectant hand sanitizer-jiuke

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)

Isopropyl 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.

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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

80 ml NDC: 76672-003-02

FORTASTE[®]
INSTANT HAND SANITIZER NET:80ml

Product Introduction:
1.Safety proven product
2.Kills 99.9% of germs
Contains moisturizing ingredient
Moisturizing effect considering skin health
INSTANT HAND SANITIZER
Kill bacteria and virus
To protect your health

INGREDIENTS: ETHANOL, WATER, GLYCERIN, CARBOMER, PEG-40 HYDROGENATED CASTOR OIL, TRIETHANOLAMINE, ESSENCE.

Active Ingredients And Content: Ethanol75±5% (v/v)

Inhibition type: E. coli, Staphylococcus aureus

How to use: Take an appropriate amount of this product on the hands, repeatedly massage until dry, without washing.

Note: If you feel uncomfortable, please stop using it. Avoid direct contact with the eyes. If you accidentally get into your eyes, please wash it with water immediately. Do not eat. Keep it dry and protected from light. Use as soon as possible after opening.

Storage method: Please store in a cool and dry place and keep it sealed.

Executive standard: Q/JKJG 18
Approval No.: [Nz2014-01] - 01 - No. 8012
Manufacturer: Guangzhou Jiuke Fine Chemical Co., Ltd.
Manufacturer address: No. 9, Sanheng Road, Zhenhua North Road, Shenshan, Jianggao Town, Baiyun District, Guangzhou
Place of Origin: Guangdong, Guangzhou
Shelf life: two years **Phone:** 020-84063099
Production batch number and deadline for use:
See packaging (please use before the expiration date)

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DISINFECTANT HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76672-003	
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		
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:76672-003-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
2	NDC:76672-003-02	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
3	NDC:76672-003-03	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
4	NDC:76672-003-04	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
5	NDC:76672-003-05	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
6	NDC:76672-003-06	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/30/2020		

Labeler - Guangzhou Jiuke Fine Chemical Co., Ltd. (554529389)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Jiuke Fine Chemical Co., Ltd.		554529389	manufacture(76672-003)