

BACTERICIDAL DISINFECTANT- isopropyl alcohol spray
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.

Bactericidal disinfectant-guangzhou 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

FORTASTE®

NET:100ml

BACTERICIDAL DISINFECTANT

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, BACTERIOSTATIC AGENT.

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

Inhibition type: E. coli, Staphylococcus aureus

How to use: Spray this product on hands, masks, clothes, objects, air, etc.

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/ JK.DXHG 18

Approval No: [Yue] wxzz [2016] - 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:** 020-86063099

Production batch number and deadline for use:

See packaging [please use before the expiration date]



100 ml NDC: 76672-001-03

BACTERICIDAL DISINFECTANT

isopropyl alcohol spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76672-001 |
| 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:76672-001-01 | 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:76672-001-02 | 80 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:76672-001-03 | 100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:76672-001-04 | 150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 5 | NDC:76672-001-05 | 300 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 6 | NDC:76672-001-06 | 1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 7 | NDC:76672-001-07 | 5000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 03/30/2020 | |
| 8 | NDC:76672-001-09 | 500 mL in 1 BOTTLE, SPRAY; 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 - Guangzhou Jiuke Fine Chemical Co., Ltd. (554529389)

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| Guangzhou Jiuke Fine Chemical Co., Ltd. | | 554529389 | manufacture(76672-001) |