

75% ETHANOL WASH FREE HAND SANITIZER GEL- isopropyl alcohol gel JIANGXI CHIEF INDUSTRIAL 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-Jiangxi Chief

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.

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.

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

60 ml NDC: 75524-001-01

  WITH MOISTURIZERS	<p>DRUG FACTS</p> <table border="1"> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Ethyl Alcohol 75%</td> <td>Antiseptic</td> </tr> </table> <p>Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use • In children less than 2 months of age. • On open skin wounds.</p> <p>When using this product Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>OTC - Stop use and ask a doctor If irritation or rash occurs. These may be signs of serious conditions.</p> <p>OTC - Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Other information • Store between 15°C-30°C (59°F-86°F) • Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive ingredients Distilled and deionized water, Glycerin, Carbomer, Triethanolamine</p>	Active ingredient	Purpose	Ethyl Alcohol 75%	Antiseptic
Active ingredient	Purpose				
Ethyl Alcohol 75%	Antiseptic				
KILLS 99.99% OF GERMS	Manufacturer: Jiangxi Chief Industrial Co., Ltd. No. 1866 Chief Industrial Park, Dongsheng Avenue, Nanchang City, Jiangxi Province, China 330012 Product Number: EXP Date: On the bottle Made in China				
2 FL OZ / 60mL	 6 958505 908250				

75% ETHANOL WASH FREE HAND SANITIZER GEL

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75524-001
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
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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)	

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75524-001-01	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/28/2020	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/28/2020	

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Labeler - JIANGXI CHIEF INDUSTRIAL CO., LTD (544328452)

Registrant - JIANGXI CHIEF INDUSTRIAL CO., LTD (544328452)

Establishment

Name	Address	ID/FEI	Business Operations
JIANGXI CHIEF INDUSTRIAL CO., LTD		544328452	manufacture(75524-001)

Revised: 4/2020

JIANGXI CHIEF INDUSTRIAL CO., LTD