HAND SANITIZER- isopropyl alcohol liquid 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 SANTIZER

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

2000 ml NDC: 75524-005-01



Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75524-005		
Route of Administration	TOPICAL				

0	Active Moiety				
Ingredient Name			Basis of Stren	ngth	Strength
SOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - INII:ND2M416302)			ISOPROPYL Alcohol		mL 100 mL
Inactive Ingredien	nts				
Ingredient Name			Strength		
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL		
WITTER (OTH. 055QP01	KOOR)				
Packaging		Marketii	ng Start Date	Marketi	ng End Dat
Packaging # Item Code	KOOR) Package Description 000 mL in 1 BOTTLE; Type 0: Not a Combination Product		ng Start Date 0	Marketi	ng End Dat
1 NDC:75524-005-01 2	Package Description 000 mL in 1 BOTTLE; Type 0: Not a Combination Product		-	Marketi	ng End Dat
Packaging # Item Code	Package Description 000 mL in 1 BOTTLE; Type 0: Not a Combination Product prmation	04/30/202	0		
Packaging # Item Code 1 NDC:75524-005-01 2 Marketing Info	Package Description 000 mL in 1 BOTTLE; Type 0: Not a Combination Product ormation y Application Number or Monograph Citation	04/30/202	0 ng Start Date		ng End Dat ng End Date

Labeler - JIANGXI CHIEF INDUST RIAL CO.,LTD (544328452)

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

Establishment

Name	Address	ID/FEI	Business Operations
JIANGXI CHIEF INDUSTRIAL CO.,LTD		544328452	manufacture(75524-005)

Revised: 5/2020

JIANGXI CHIEF INDUSTRIAL CO.,LTD