# HAND SANITIZER- is opropyl alcohol gel KeRuiSi Cosmetics (Jinhua) 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.

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### 2X 60ml Hand Sanitizer

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)

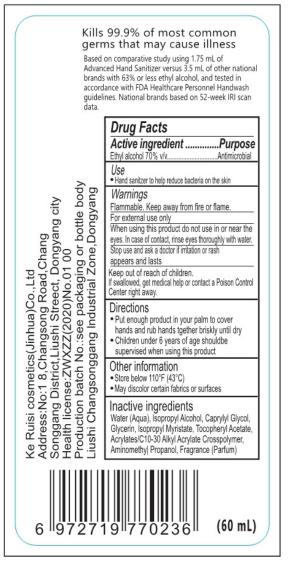
# **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## **Package Label - Principal Display Panel**

60 ml NDC: 55422-015-01





# HAND SANITIZER

isopropyl alcohol gel

<b>Product Information</b>	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55422-015	
Route of Administration	EXTRACORPOREAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
TOCOPHERYL RETINOATE (UNII: 0WN694NBMM)		
WATER (UNII: 059QF0KO0R)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
PERFLUORO ALKYLETHYL ACRYLATES (C6-C14) (UNII: TKA54G588X)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)		

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

F	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55422-015-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	



#### Kills 99.9% of most common germs that may cause illness

Based on comparative study using 1.75 mL of Advanced Hand Sanitizer versus 3.5 mL of other national brands with 63% or less ethyl alcohol, and tested in accordance with FDA Healthcare Personnel Handwash guidelines. National brands based on 52-week IRI scan data.

# Drug Facts Active ingredient . .Purpose Ethyl alcohol 70% v/v.. Use • Hand sanitzer to help reduce bacteria on the skin Warnings Flammable. Keep away from fire or flame.

Ke Ruisi cosmetics(Jinhua)Co., Lua Address:No:1 8, Changsong Road, Chang Songgang District, Liushi Streect, Dongyang city Health license: ZWXZZ(2020)No:01 00 Production batch No.:see packaging or bottle body Liushi Changsonggang Industrial Zone, Dongyang For external use only
When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions . Put enough product in your palm to cover hands and rub hands tgether briskly until dry

. Children under 6 years of age shouldbe supervised when using this product

#### Other information

- Store below 110°F (43°C)
- . May discolor certain fabrics or surfaces

### Inactive ingredients

Water (Aqua), Isopropyl Alcohol, Caprylyl Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethy| Propanol, Fragrance (Parfum)



(60 mL)

# **Marketing Information**

**Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date** OTC monograph not final part333A 03/30/2020

# Labeler - KeRuiSi Cosmetics (Jinhua) Co.,Ltd. (554532199)

Establishment			
Name	Address	ID/FEI	Business Operations
Ke RuiSi Cosmetics (Jinhua) Co.,Ltd.		554532199	manufacture (55422-015)

Revised: 5/2020 KeRuiSi Cosmetics (Jinhua) Co.,Ltd.