

HAND SANITIZER- isopropyl 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.

2X 500 ml 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

500 ml NDC: 55422-017-01

SCHOOL BONUS 50% MORE FREE

2X SANITIZING STRENGTH
1 SQUIRT Sanitizer 2 SQUIRTS Other National Brands

Kills 99.9% of most common germs that may cause illness
Based on comparative study using 1.75mL of Advanced Hand Sanitizer versus 3.5mL 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 scandata.

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

Ke RuiSi cosmetics (Jinhua) Co., Ltd
Address: No.118, Changgong Road, Chang Songgang District, Luoshi Street, Dongyang city, Health license: ZWZZZ2020 No.01 00
Production batch No.: see packaging or bottle body
Luoshi Changsonggang Industrial Zone, Dongyang

Sanitizer
ADVANCED HAND SANITIZER
KILLS 99.9% OF MOST ILLNESS CAUSING GERMS
Sanitizer with Triple Action Moisturizers 17FL OZ (500mL)

Drug Facts
Active ingredient **Purpose**
Ethyl alcohol 70% V..... Antimicrobial
Use:
Hand sanitizer to help reduce bacteria on the skin.
Warnings: Flammable. Keep away from fire or flame. 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.

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Directions
• Put enough product in your palm to cover hands and rub hands together briskly until dry
• Children under 6 years of age should be supervised when using this product

Other information
• Store below 110°F (43°C)
• May discolor certain fabrics or surfaces

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55422-017
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
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
TOCOPHERYL RETINOATE (UNII: 0WN694NBMM)	
WATER (UNII: 059QF0KOOR)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

PERFLUOROALKYLETHYL ACRYLATES (C6-C14) (UNII: TKA54G588X)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55422-017-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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Ke RuiSi cosmetics (Jinhua) Co., Ltd
Address: No.18 Changsong Road, Changsonggang District, Lushi Street, Dongyang city. Health license: 242221(2020) No.51 00
Production batch No. see packaging or bottle body. Lushi Changsonggang Industrial Zone, Dongyang

Sanitizer
ADVANCED HAND SANITIZER
KILLS 99.9% OF MOST ILLNESS CAUSING GERMS
Sanitizer
with Triple Action Moisturizers
17FL OZ (500mL)

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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(55422-017)

Revised: 5/2020

KeRuiSi Cosmetics (Jinhua) Co.,Ltd.