

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 Hand Sanitizer 236ml

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

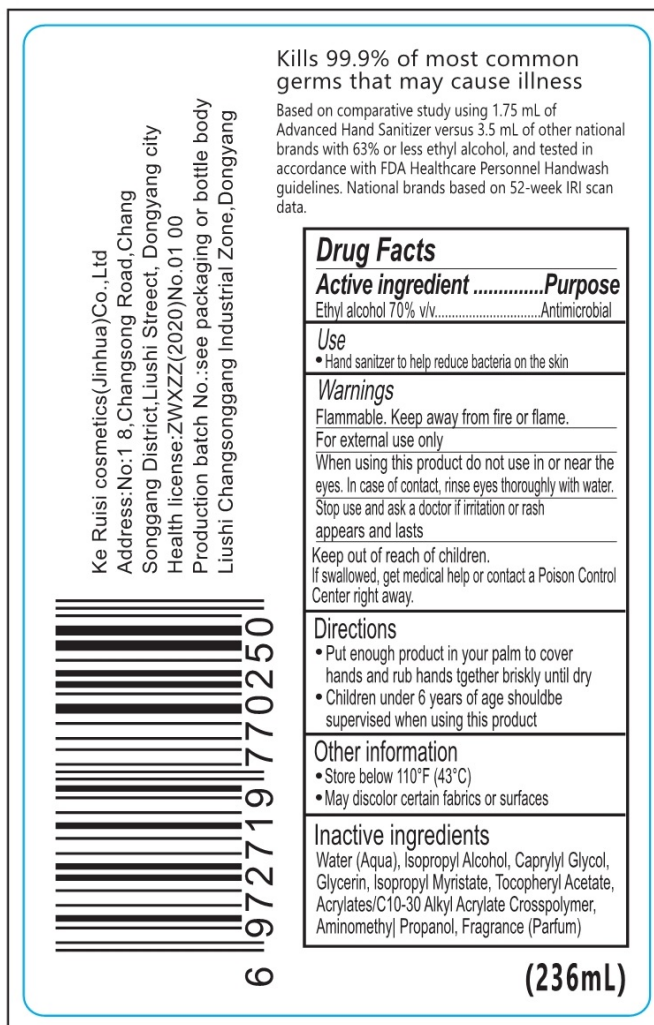
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

236 ml NDC: 55422-013-01



HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55422-013
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)	
TOCOPHERYL RETINOATE (UNII: 0WN694NBMM)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0K00R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
PERFLUOROALKYLETHYL ACRYLATES (C6-C14) (UNII: TKA54G588X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55422-013-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

SCHOOL BONUS  **50% MORE FREE**

2X SANITIZING STRENGTH*

1 SQUIRT Sanitizer Hand Sanitizer  =  2 SQUIRTS Other National Brands

Sanitizer

ADVANCED HAND SANITIZER

KILLS 99.9% OF MOST ILLNESS CAUSING GERMS

Sanitizer


with Triple Action Moisturizers

7.9 FL OZ (236 mL)

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.

Ke RuiSi cosmetics(Jinhua)Co.,Ltd
Address:No.1 8,Changsong Road,Chang Songgang District,Liushi Street, Dongyang city
Health license:ZWZZ(2020)No.01 00
Production batch No.:see packaging or bottle body
Liushi Changsonggang Industrial Zone,Dongyang

 6 972719 770250

Drug Facts

Active ingredient	Purpose
Ethyl alcohol 70% v/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 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 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	
Inactive ingredients	
Water (Aqua), Isopropyl Alcohol, Caprylyl Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance (Parfum)	

(236mL)

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(55422-013)

Revised: 5/2020

KeRuiSi Cosmetics (Jinhua) Co.,Ltd.