

ANTIBACTERIAL FREE GEL- alcohol liquid
Guangzhou Xin Qi Cosmetics 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.

Antibacterial free gel

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. WATER
- c. CARBOMER
- d. TRIETHANOLAMINE

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)

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

WATER
CARBOMER
TRIETHANOLAMINE

Package Label - Principal Display Panel

PRUKSAPORN WASH FREE HAND SANITIZER GEL

Bactericidal Microorganisms that can be sterilized with this product: Escherichia coli, Staphylococcus aureus, candida albicans, mold, etc.

PRODUCT EFFICACY:
Disinfection and bactericidal ingredients included, effectively eliminate and inhibit the production and replication of harmful bacteria. It is a general antiseptic. It can be used repeatedly every day, which helps to keep hands clean and bring health to family.

COMPONENT: ALCOHOL • WATER • CARBOMER • TRIETHANOLAMINE



WASH FREE HAND SANITIZER GEL
75% Alcohol
1L. 31.4fl. oz

USAGE:
Apply appropriate amount to palm and rub it to evaporate naturally without washing.

NOTES:
For external use only. Avoid contacting with children. If in eyes, rinse well with water. This product has a high alcohol content, please stay away from fire, using with caution if allergy to alcohol.

Manufacturer: Guangzhou Xinqi Cosmetics Co., Ltd
Address: No. 3 floor, No. 101 factory, No. 18, tangziling, Zhongluotan Town, Baiyun District, Guangzhou
Production enterprise health license No.: ywzz (2020) - 01-8059
Executive standard: Q/JZRH9-2020
Place of origin: Guangdong • Guangzhou
inspection qualified
Production batch number and expiration date: see the mark
MADE IN CHINA



ANTIBACTERIAL FREE GEL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78370-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78370-101-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78370-101-02	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78370-101-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78370-101-04	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78370-101-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:78370-101-06	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:78370-101-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:78370-101-08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:78370-101-09	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:78370-101-10	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:78370-101-11	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
12	NDC:78370-101-12	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
13	NDC:78370-101-13	1500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
14	NDC:78370-101-14	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
15	NDC:78370-101-15	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
16	NDC:78370-101-16	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
17	NDC:78370-101-17	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
18	NDC:78370-101-18	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
19	NDC:78370-101-19	8 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
20	NDC:78370-101-20	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
21	NDC:78370-101-21	3 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Xin Qi Cosmetics Co., Ltd.		403016583	manufacture(78370-101)

Revised: 5/2020

Guangzhou Xin Qi Cosmetics Co., Ltd.