

ANTIBACTERIAL HAND SANITIZER GEL- alcohol liquid
Yaer Baizi Import and Export Trade (Guangzhou) 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 hand sanitizer 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) (75%, 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. Aqua
- 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.

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

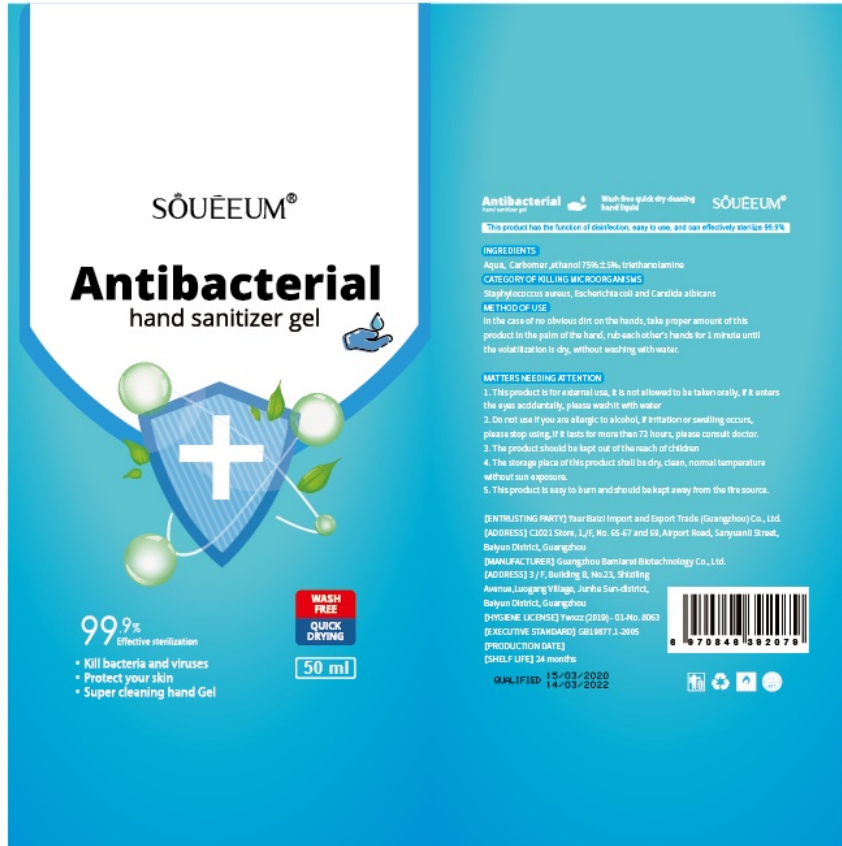
Aqua
Carbomer
triethanolamine

Package Label - Principal Display Panel

免洗净手消毒凝胶

标签尺寸:107mmx107mm

净含量:50ML



标签尺寸:107mmx107mm

净含量:50ML

免洗净手消毒凝胶

标签尺寸:142mmx107mm

标签尺寸:142mmx107mm
净含量:98ML



The image shows a vertical label for 'SOUËEUM® Antibacterial hand sanitizer gel'. The label is primarily blue and white. At the top, the brand name 'SOUËEUM®' is displayed. Below it, the product name 'Antibacterial hand sanitizer gel' is written in a large, bold font, accompanied by a small icon of a hand being washed. The central graphic features a shield with a white cross, surrounded by green leaves and bubbles, symbolizing protection and freshness. A red and white box on the right side of the shield reads 'WASH FREE QUICK DRYING'. Below the shield, the text '99.9% Effective sterilization' is prominently displayed, followed by three bullet points: 'Kill bacteria and viruses', 'Protect your skin', and 'Super cleaning hand Gel'. At the bottom left, a white box contains '98 ml'. The right side of the label is a light blue background containing detailed product information in English, including ingredients, category of killing microorganisms, method of use, matters needing attention, and contact information for the entrusting party. A barcode is located at the bottom right of this section.

SOUËEUM®

Antibacterial
hand sanitizer gel

WASH FREE
QUICK DRYING

99.9%
Effective sterilization

- Kill bacteria and viruses
- Protect your skin
- Super cleaning hand Gel

98 ml

Antibacterial
For all weather use

Wash free quick dry cleaning
hand liquid

SOUËEUM®

This product has the function of disinfection, easy to use, and can effectively sterilize 99.9%.

INGREDIENTS
Aqua, Carbomer, ethanol 75%±9%, triethanolamine

CATEGORY OF KILLING MICROORGANISMS
Staphylococcus aureus, Escherichia coli and Candida albicans

METHOD OF USE
In the case of no obvious dirt on the hands, take proper amount of this product in the palm of the hand, rub each other's hands for 1 minute until the volatilization is dry, without washing with water.

MATTERS NEEDING ATTENTION

1. This product is for external use, it is not allowed to be taken orally, if it enters the eyes accidentally, please wash it with water.
2. Do not use if you are allergic to alcohol, if irritation or swelling occurs, please stop using, if it lasts for more than 72 hours, please consult doctor.
3. The product should be kept out of the reach of children.
4. The storage place of this product shall be dry, clean, normal temperature without sun exposure.
5. This product is easy to burn and should be kept away from the fire source.

[ENTRUSTING PARTY] Yaer Balz Import and Export Trade (Guangzhou) Co., Ltd.
[ADDRESS] C1021 Store, 1/F, No. 65-67 and 69, Airport Road, Sanyuanli Street, Baiyun District, Guangzhou

[MANUFACTURER] Guangzhou Barnland Biotechnology Co., Ltd.
[ADDRESS] 3/F, Building B, No.23, Shiziling Avenue, Luogang Village, Junhe Sun-district, Baiyun District, Guangzhou

[HYGIENE LICENSE] Ywzzz (2019) - 01-No. 8063
[EXECUTIVE STANDARD] GB19877.1-2005
[PRODUCTION DATE]
[SHELF LIFE] 24 months

6 970846 192062

15/03/2020
14/03/2022

标签尺寸:142mmx107mm
净含量:98ML

免洗净手消毒凝胶

标签尺寸:116mmx75mm
净含量:100ML



标签尺寸:116mmx75mm
净含量:100ML

免洗净手消毒凝胶

净含量: 250ML
标贴尺寸: 175mmX70mm



正标

背标

标贴尺寸: 175mmX70mm

净含量: 250ML

免洗净手消毒凝胶

净含量: 300ML

标贴尺寸: 193X69



标贴尺寸: 193mmX69mm

净含量: 300ML

正标

背标

免洗净手消毒凝胶

标签尺寸: 210mmx100mm

净含量: 500ML



标签尺寸: 210mmx100mm

净含量: 500ML

免洗净手消毒凝胶

净含量：1000ML

标贴尺寸：230mmX160mm



正标

背标

标贴尺寸：230mmx160mm

净含量：1000ML

ANTIBACTERIAL HAND SANITIZER GEL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75240-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75240-101-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75240-101-02	98 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75240-101-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75240-101-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75240-101-05	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75240-101-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75240-101-07	1000 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	

Labeler - Yaer Baizi Import and Export Trade (Guangzhou) Co., Ltd. (403080078)

Establishment

Name	Address	ID/FEI	Business Operations
Yaer Baizi Import and Export Trade (Guangzhou) Co., Ltd.		403080078	manufacture(75240-101)

Revised: 4/2020

Yaer Baizi Import and Export Trade (Guangzhou) Co., Ltd.