

(FRULI) HAND ANTISEPTIC RINSE FREE GEL- alcohol gel
Shandong Zhuojian Medical Technology 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.

Hand Antiseptic Rinse 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. 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)

Alcohol 54%-66% v/v. Purpose: Antiseptic

n-propanol 9%-11%. 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

100 mL NDC: 77442-003-02

ISO9001 Quality System
Certification Enterprise
Comply with U.S. FDA
Regulation

External
use

CE

Fruli®
**Hand Antiseptic
Rinse Free Gel**

Long-term sterilization
Staphylococcus aureus
Escherichia coli
Pseudomonas aeruginosa
Candida albicans

Bottle: 100ml

Shandong Zhuojian Medical Technology Co., Ltd.

[Main active ingredients and content] This product is a disinfecting gel with ethanol and n-propanol as the main active ingredients. The ethanol content is 54%-66% (v / v), and the n-propanol content is 9%-11% (v / v).

[Formulation] Gel

[Killing microbe category] It can kill intestinal pathogenic bacteria, pyrogenic coccus, pathogenic yeast and common bacteria in hospital

[Scope of use] Suitable for surgical hand disinfection and sanitary hand disinfection

[Instructions]

1. Surgical hand disinfection: After washing hands and forearms with soap solution, take about 5-10ml of this product, and rub hands and forearms evenly according to the hand washing method specified in "Disinfection Technical Specifications", rub for about 3min to dry. You can wear sterile gloves
2. Hygienic hand disinfection: Take 3ml of this product and rub your hands together for about 1min

[Precautions]

1. Disinfectant for external use should not be taken orally. Keep out of reach of children
2. This product contains ethanol, avoid open flames, irritating to damaged skin and mucous membranes, and those who are allergic to ethanol are prohibited.
3. Sealed and stored in a cool, ventilated and dry place.

[Validity] 24 months
[Executive Standard] Q / 37140 ZSDZJ008
[Production Enterprise Health License Number]
Lu Wei Xiao Zheng Zi (2017) No. 1309
[Manufacturer name]
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[Postal code] 253000
[Telephone / Fax] 0534-2731666
[Service Phone] 4006-536-828
[URL] www.zhuojianjic.com
[Production date] see code **[Production batch number]** see code **[Valid until]** see code

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(FRULI) HAND ANTISEPTIC RINSE FREE GEL

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77442-003

Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	66 mL in 100 mL	
PROPYL ALCOHOL (UNII: 96F264O9SV) (PROPYL ALCOHOL - UNII:96F264O9SV)		PROPYL ALCOHOL	11 mg in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77442-003-01	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77442-003-02	100 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77442-003-03	250 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77442-003-04	500 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
5	NDC:77442-003-05	1000 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
6	NDC:77442-003-06	5000 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
7	NDC:77442-003-07	3 mL in 1 BAG; Type 0: Not a Combination Product	05/01/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/01/2020	

Labeler - Shandong Zhuojian Medical Technology Co., Ltd. (419225475)

Registrant - Shandong Zhuojian Medical Technology Co., Ltd. (419225475)

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Zhuojian Medical Technology Co., Ltd.		419225475	manufacture(77442-003)