

**(FRULI) 75% ALCOHOL DISINFECTANT- alcohol liquid**  
**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.*

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**Fruli® 75% alcohol disinfectant-Zhuojian**

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 80% 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: 77442-001-04

**Shandong Zhuojian Medical Technology Co., Ltd.**

**Fruli 75% alcohol disinfectant**

**bottle 500ml**

**External use**

**ISO9001 Quality Certificate**

**【Main active ingredients and content】** Ethanol, content 75% ± 5% (v / v).

**【Killing microorganisms category】** This product can kill general bacterial propagules such as intestinal pathogenic bacteria, pyogenic cocci and pathogenic yeast.

**【Scope of use】** Suitable for disinfection of general object surfaces and intact skin surfaces.

**【Usage method】** Scrub disinfection of the original solution, the action time is 1-3min.

**【Precautions】** 1. This product is for external use and should not be taken orally; 2. Use with caution for those allergic to ethanol; 3. Sealed and protected from light; 4. This product is flammable and should be kept away from fire sources.

**【Validity】** Two years **【Executive Standard】** Q / 371402SDZJ005

**【Production Enterprise Health License Number】** Lu Wei Xiao Zheng Zi (2017) No. 1309

**【Production Unit Name】** Shandong Zhuojian Medical Technology Co., Ltd.

**【Address of Production Unit】** No. 2558, Chongde 5th Avenue, Yuanqiao Town, Dezhou Economic and Technological Development Zone, Shandong Province, China. **【Postal code】** 253000

**【Telephone】** +86-534-2731666 / 4006-536-828

**【Website】** www.zhuojiankeji.com

**【Production Date】** see code

**【Serial Number】** see code

**【Valid until】** see code

**6 971227 730206**

**Excellent quality, healthy life**

### (FRULI) 75% ALCOHOL DISINFECTANT

alcohol liquid

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77442-001
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL 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:77442-001-01	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77442-001-02	100 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77442-001-03	250 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77442-001-04	500 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	05/01/2020	
5	NDC:77442-001-05	2500 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/01/2020	
6	NDC:77442-001-06	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/01/2020	
7	NDC:77442-001-07	25000 mL in 1 CONTAINER; 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(77442-001)

Revised: 5/2020

Shandong Zhuojian Medical Technology Co., Ltd.