

(FRULI) QUICK-DRY DISPOSABLE HAND SANITIZER- 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.

Quick-Dry Disposable Hand Sanitizer

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



ISO9001 Quality Certificate



Fruli
芙润莱

**Quick-Dry Disposable
Hand Sanitizer**

**External
use**

Net Content: 500ml

【Main active ingredients and content】 This product uses chlorhexidine gluconate and ethanol as the main active ingredients. The content of chlorhexidine gluconate is 0.5% ± 0.05% (w/v) and the content of ethanol is 70% ± 7% (v/v).

【Killer Microbial Category】 Can kill intestinal pathogenic bacteria, pyrogenic cocci, pathogenic yeast and common bacteria in hospital infection.

【Scope of use】 1. Sanitary hand disinfection; 2. Surgical hand disinfection; 3. Skin disinfection; 4. Complete skin disinfection at the surgical site.

【Usage】 Spray and rub the disinfected part for 1-3min.

【Precautions】 1. Do not take oral disinfectant. Keep out of reach of children; 2. This product is used for clean and dry hands; 3. This product contains ethanol, which is irritating to damaged skin and mucous membranes, and those who are allergic to ethanol are prohibited; Office.

【Validity】 24 months **【Executive Standard】** Q / 371402SDZJ028

【Production Enterprise Health License Number】

Lu Wei Xiao Zheng Zi (2017) No. 1309

【Manufacturer name】 Shandong Zhuojian Medical Technology Co., Ltd.

【Manufacturer address】 No. 2558, Chongde 5th Avenue, Dezhou Economic and Technological Development Zone, Shandong Province, china

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【Telephone / Fax】 0534-2731666

【Service Phone】 4006-536-828

【URL】 www.zhuojiankeji.com

【Date of manufacture】 see code

【Lot number】 see code

【Valid until】 see code



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Shandong Zhuojian Medical Technology Co.,Ltd

500 mL NDC: 77442-002-04

(FRULI) QUICK-DRY DISPOSABLE HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77442-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	0.5 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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77442-002-01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2020	
2	NDC:77442-002-02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2020	
3	NDC:77442-002-03	250 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2020	
4	NDC:77442-002-04	500 mL in 1 BOTTLE, SPRAY; 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(77442-002)

Revised: 5/2020

Shandong Zhuojian Medical Technology Co., Ltd.