

75% ALCOHOL DISINFECTANT- 75% alcohol disinfectant liquid
Zhejiang Dongyang Medical & Hygienic Articles 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.

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 DENAT. 70%

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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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, Propylene Glycol, Glycerin, CARBOMER, AMINOMETHYL PROPANOL

Package Label - Principal Display Panel



75% DISINFECTANT

Main active ingredients: Ethanol 75% \pm 5%

Efficacy: Efficient to kill Staphylococcus aureus, E. coli, Pseudo-monas aeruginosa and Candida albicans etc.

Use range: Hand disinfection, general object surface disinfection.

Usage and dosage:

1. Hand disinfection: follow the standard method to use soap to wash hands, rinse with running water, dry with sterile towels, then direct spray this product on hands and forearms until moist, wait for 3 minutes, rub hands until dry.
2. General object surface disinfection: directly spray on the object surface for until moist, wait for 3-5 minutes.

CAUTION:

1. EXTREMELY FLAMMABLE. pressurized container; protect from sunlight and don't expose to temperatures exceeding 50 C. Don't pierce or burn, even after use. Don't spray on a naked flame or any incandescent material. Keep it away from the reach of children. Don't spray towards eyes.
2. External disinfectant should not be taken orally and kept out of reach of children.
3. Use with caution if allergic to alcohol.
4. It should not be used to disinfect fat-soluble surfaces.
5. This product is irritating to wounds and mucous membranes.

MANUFACTURER:

DONGYANG MEDICAL & HYGIENIC ARTICLES CO.,LTD.



75% ALCOHOL DISINFECTANT

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53031-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	150 mL in 200 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	SHUANGNIAO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53031-014-01	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020	

Marketing Information

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

Labeler - Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd. (530310429)**Establishment**

Name	Address	ID/FEI	Business Operations
Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd.		530310429	manufacture(53031-014)

Revised: 5/2020

Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd.