

75% ALCOHOL DISINFECTANT- 75% alcohol disinfectant liquid
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.

81276-016 1L DONGYANG MEDICAL

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 75% v/v. Purpose: Antiseptic,Disinfection

Purpose

Efficacy:

Efficient to kill Staphylococcus aureus,Escherichia coil,Pseudo monas aeruginosa and Candida alibicans etc.

Application:

Hand disinfection and general object surface disinfection.

Use

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.

Warnings

1.EXTREMELY FLAMMABLE:

seal preservation, keep away from sunlight perpendicular incidence place and don't expose to temperatures exceeds 50°.Don't pierce or burn, even after use. Don't spray on a naked flame or any flammable 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.

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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Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 50C (104F)

Inactive ingredients

purified water USP

Package Label - Principal Display Panel

1L NDC: 81276-016-01



75% ALCOHOL DISINFECTANT

75% alcohol disinfectant liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:8 1276-0 16
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	750 mL in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:8 1276-0 16-01	1 L 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 - Dongyang Medical & Hygienic Articles Co., Ltd. (530310429)

Registrant - Dongyang Medical & Hygienic Articles Co., Ltd. (530310429)

Establishment

Name	Address	ID/FEI	Business Operations
Dongyang Medical & Hygienic Articles Co., Ltd.		530310429	manufacture(81276-016)

Revised: 12/2020

Dongyang Medical & Hygienic Articles Co., Ltd.