#### 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.

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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.

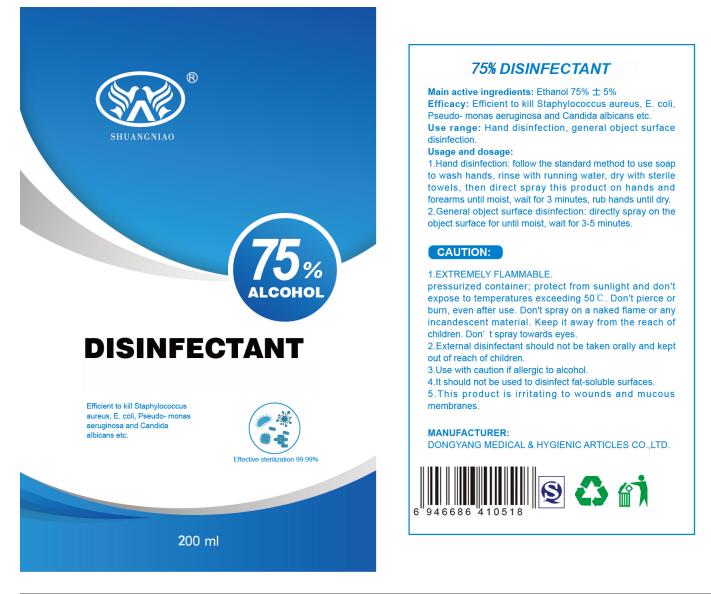
### Other information

- 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% ALCOHOL DISINFECTANT**

75% alcohol disinfectant liquid

Product Information									
Product Type		HUMAN OTC DRUG	HUMAN OTC DRUG Item Co			NDC:53031-014			
Route of Administra	ation	TOPICAL							
Active Ingredient/Active Moiety									
	0	redient Name		Basis of Str		Strength			
ALCOHOL (UNII: 3KS	9958V90M) (A	ALCOHOL - UNII:3K9958V9	90M)	ALCOHOL		150 mL in 200 mL			
Inactive Ingredie	ents								
		Ingredient Name	gredient Name			Strength			
WATER (UNII: 059QF									
Product Characteristics									
Color		Score							
Shape		Size							
Flavor		Imprint Code	Imprint Code		GNIAO				
Contains									
Packaging									
# Item Code		Package Description	ckage Description Marketin		tart Date	Marketing End Date			
<b>1</b> NDC:53031-014-01 200 mL in 1 BOTTL		BOTTLE; Type 0: Not a Con	nbination Product	05/06/2020					
Marketing Information									
Marketing Catego	keting Category Application		n Number or Monograph Citation		tart Date	Marketing End Date			
OTC monograph not fi	TC monograph not final part333A			03/30/2020					

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

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

Revised: 5/2020

Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd.