

**HAND SANITIZER- alcohol gel**  
**ZHEJIANG SHUNAN INDUSTRY&TRADE 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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**75556-999 1000 ml SHUNAN 11754-999 Puranic, Inc**

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

**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**

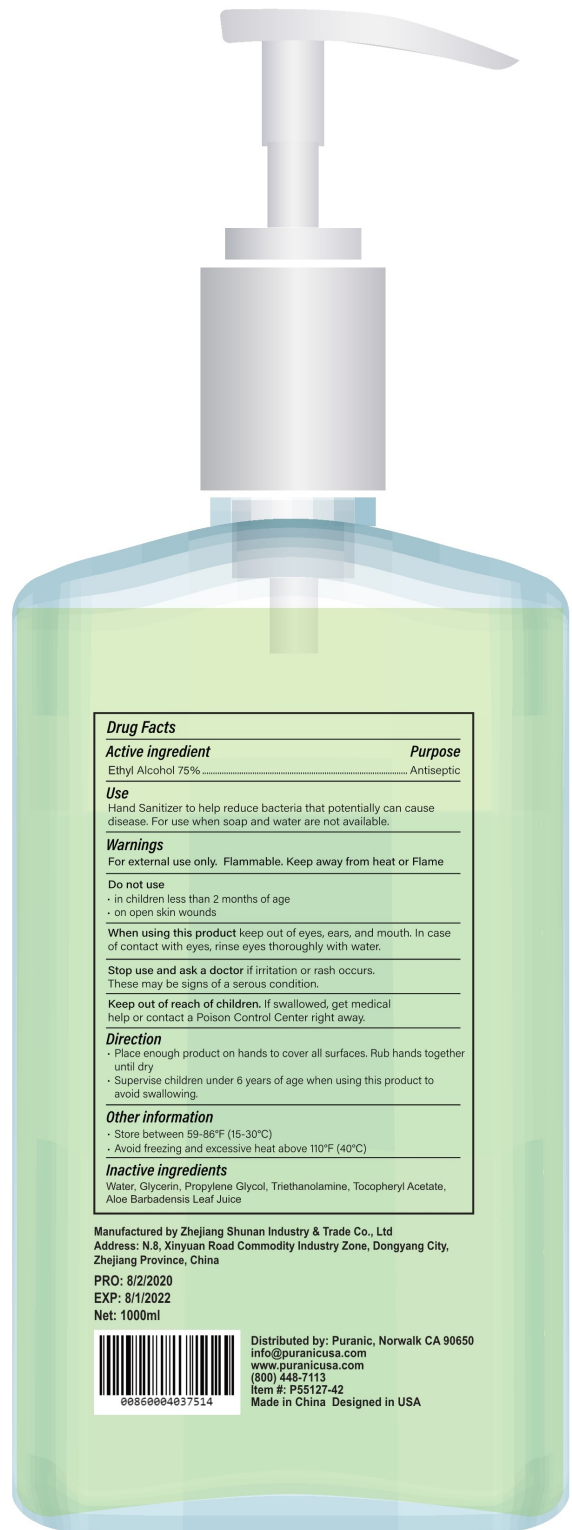
- Store between 59-86°(15-30° )
- Avoid freezing and excessive heat above 110°(40° )

**Inactive ingredients**

Water,Glycerin,Propylene Glycol, Triethanolamine,Tocopheryl Acetate,Aloe Barbadensis Leaf Juice

**Package Label - Principal Display Panel**

1000 mL in 1 Bottle NDC: 75556-999-01



## HAND SANITIZER

alcohol gel

### Product Information

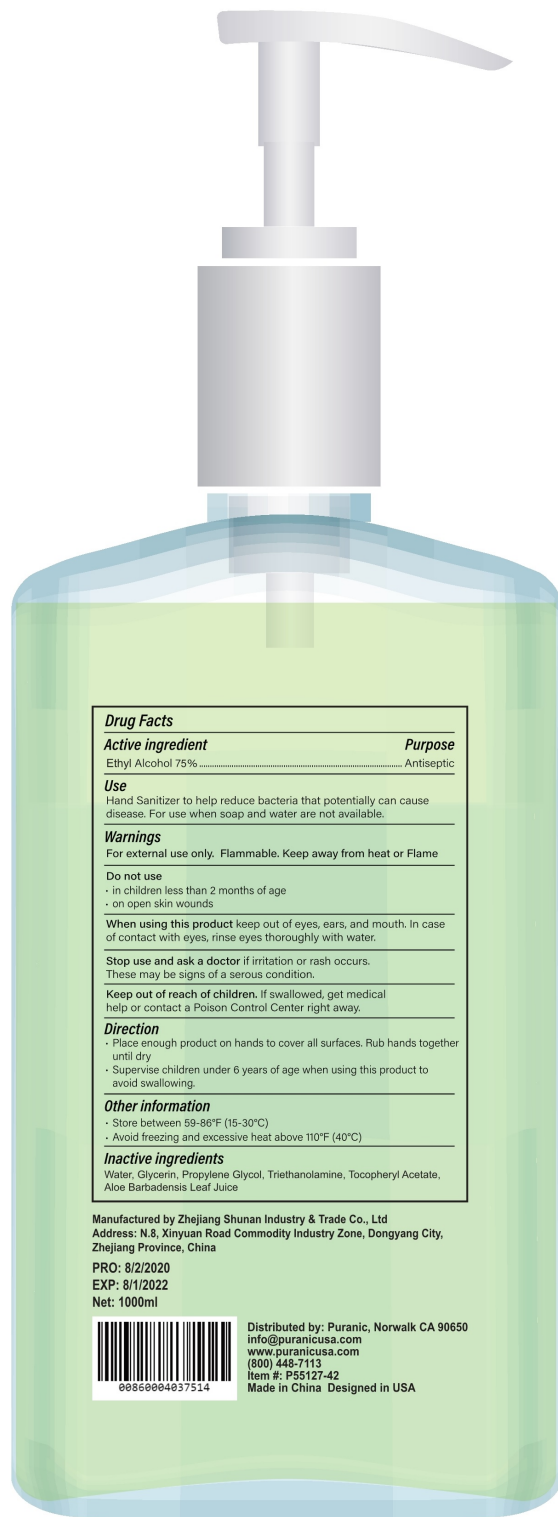
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75556-999
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	750 mL in 1000 mL

Inactive Ingredients	
Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75556-999-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

**Labeler** - ZHEJIANG SHUNAN INDUSTRY&TRADE CO.,LTD (528198838)

**Registrant** - ZHEJIANG SHUNAN INDUSTRY&TRADE CO.,LTD (528198838)

## Establishment

Name	Address	ID/FEI	Business Operations
ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD		528198838	manufacture(75556-999)

Revised: 7/2020

ZHEJIANG SHUNAN INDUSTRY&TRADE CO.,LTD