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.

7556-0061000 ml

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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

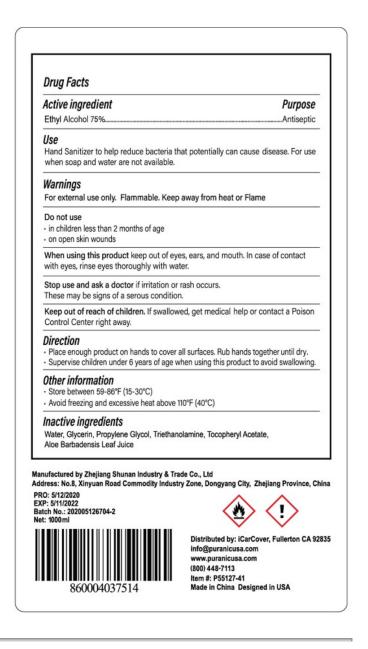
Inactive ingredients

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

Package Label - Principal Display Panel

1000 mL in 1 Bottle NDC: 75556-006-01





HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75556-006	
Route of Administration	EXTRACORPOREAL			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
TROLAMINE (UNII: 9O3K93S3TK)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:75556-006-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020		



Drug Facts

Active ingredient

Purpose

Ethyl Alcohol 75%. .Antiseptic

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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 serous condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

- · 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°F (15-30°C)
- · Avoid freezing and excessive heat above 110°F (40°C)

Inactive ingredients

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

Manufactured by Zhejiang Shunan Industry & Trade Co., Ltd Address: No.8, Xinyuan Road Commodity Industry Zone, Dongyang City, Zhejiang Province, China

EXP: 5/11/2022 Batch No.: 202005126704-2 Net: 1000 ml



Distributed by: iCarCover, Fullerton CA 92835 info@puranicusa.com (800) 448-7113 Item #: P55127-41

Made in China Designed in USA

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** manufacture(75556-006) ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD 528198838