

## **HAND SANITIZER- alcohol gel**

### **Puranic, Inc**

*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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### **11754-037-80 3.78L Puranic, Inc 75556-037-80SHUNAN**

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

## Inactive ingredients

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

## Package Label - Principal Display Panel

3.78 L in 1 Bottle NDC: 11754-037-80

The image displays two views of the Puranic Hand Sanitizer label for a 1-gallon (3.78L) bottle. The front panel (left) features the brand name 'Puranic' in large blue letters, with 'HAND SANITIZER' below it. A 'PREMIUM' badge is positioned above a central graphic of aloe vera leaves inside a circular frame with a plus sign and a letter 'E'. Text on the left states 'Kills 99.99% of germs within 15 seconds' and 'Aloe Vera & Vitamin E'. A '2x SANITIZING STRENGTH' badge is at the bottom left. The back panel (right) repeats the front panel's branding and includes detailed product information. It lists 'Antibacterial' (75% Ethyl alcohol), 'Antiviral' (above CDC recommendation), and 'Antioxidant' (Vitamin E) properties. It also highlights 'Soothing' properties of Aloe Vera. Three icons represent 'Vitamin E', 'Soothing Texture', and 'Gel Type'. A table of 'Drug Facts' is located on the far right, detailing the active ingredient (Ethyl Alcohol 75%), use instructions, warnings, directions, and inactive ingredients (Water, Glycerin, Propylene Glycol, Triethanolamine, Tocopheryl Acetate, Aloe Barbadosis Leaf Juice).

**Puranic**  
HAND SANITIZER

PREMIUM

Kills 99.99% of germs within 15 seconds

Aloe Vera & Vitamin E

2x SANITIZING STRENGTH

ONE GALLON (3.78L)

**Antibacterial**  
75% Ethyl alcohol

**Antiviral**  
Above CDC recommendation of 60% alcohol to ensure maximum antiviral protection

**Antioxidant**  
Vitamin E has been shown to boost skin health and quality.

**Soothing**  
Aloe Vera has proven properties that soothe and protect the hands.

Vitamin E    Soothing Texture    Gel Type

\*Effective at eliminating 99.99% of most common, harmful germs and bacteria in as little as 15 seconds. Hand sanitizer base is manufactured in an FDA-licensed facility to ensure quality and consistency.

Manufactured by Zhejiang Shuangyuan Industry & Trade Co., Ltd.  
Distributed by Puranic, Newark, CA 94560  
www.puranic.com  
800.461.7171  
Item # P1028-01  
Made in China. Designed in USA.

PRO: 8/2/2020  
EXP: 8/1/2022  
Net: 1 Gallon

**Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 75%	Antiseptic

**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. **Thrush may be sign of a serious condition.**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right 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 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 Barbadosis Leaf Juice.



## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11754-037
<b>Route of Administration</b>	EXTRACORPOREAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2.835 L in 3.78 L

### 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:11754-037-80	3.78 L in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	

**Puranic**  
HAND SANITIZER

**PREMIUM**

Kills 99.99% of germs within 15 seconds

Aloe Vera & Vitamin E

**2x** SANITIZING STRENGTH

ONE GALLON (3.78L)

**Antibacterial**  
75% Ethyl alcohol

**Antiviral**  
Above CDC recommendation of 60% alcohol to ensure maximum antiviral protection

**Antioxidant**  
Vitamin E has been shown to boost skin health and quality.

**Soothing**  
Aloe Vera has proven properties that soothe and protect the hands.

Vitamin E Soothing Texture Gel Type

\*Effective at eliminating 99.99% of most common, harmful germs and bacteria in as little as 15 seconds. Hand sanitizer is manufactured in an FDA audited facility to ensure quality and consistency.

Manufactured by Zhejiang Shunan Industry & Trade Co., Ltd.  
Address: R.L. Krizan Road  
Carenanjo Industry Zone,  
Dingyong City,  
Zhejiang Province, China

Distributed by Puranic,  
Irvine, CA 92618  
info@puranic.com  
800-685-7515  
Item # P39234-01  
Made in China, Imported in USA

PRO: 8/2/2020  
EXP: 8/1/2022  
Net: 1 Gallon

**Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 75%	Antiseptic

**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. There 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.

**Directions**  
- Place enough product on hands to cover all surfaces. Rub hands together until dry.  
- Supervise children under 8 years of age when using this product to avoid swallowing.

**Other information**  
- Store between 59°F (15-50°C)  
- Avoid freezing and excessive heat above 110°F (40°C)

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

## Marketing Information

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

**Labeler** - Puranic, Inc (117545690)

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

## Establishment

Name	Address	ID/FEI	Business Operations
ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD		528198838	manufacture(11754-037)

Revised: 7/2020

Puranic, Inc