

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.

11754-100 1000 ml

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

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 Barbadosensis Leaf Juice

Package Label - Principal Display Panel

1000 mL in 1 Bottle NDC: 11754-100-01

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	
<ul style="list-style-type: none"> 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.	
Direction	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> 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 Barbadosensis Leaf Juice	

Manufactured by Zhejiang Shunan Industry & Trade Co., Ltd
 Address: No.8, Xinyuan Road Commodity Industry Zone, Dongyang City, Zhejiang Province, China
 PRO: 5/12/2020
 EXP: 5/11/2022
 Batch No.: 202005126704-2
 Net: 1000ml

Distributed by: iCarCover, Fullerton CA 92835
 info@puranicusa.com
 www.puranicusa.com
 (800) 448-7113
 Item #: P55127-41
 Made in China Designed in USA

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11754-100
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 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:11754-100-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2020	

2x SANITIZING STRENGTH



Puranic

PREMIUM

HAND SANITIZER



Aloe Vera & Vitamin E

KILLS THE MOST GERMS

Kills **99.99%** of Germs

33.8 FL OZ (1000ml)

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860004037514

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	07/18/2020	

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(11754-100)