

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.

11754-500 500 ml s hunan 75556-502 Puranic, Inc

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.

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 Barbadosis Leaf Juice

Package Label - Principal Display Panel

500 mL in 1 Bottle NDC: 11754-500-01



LABEL SIZE : 5.5cm x 10cm

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11754-500	
Route of Administration	EXTRACORPOREAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	375 mL in 500 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)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11754-500-01	500 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 - 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(11754-500)

Revised: 11/2020

Puranic, Inc