

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.

236 ml shunan

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

236 mL NDC: 75556-007-01



label size: 5cm x 8cm

HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75556-007 |
| 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) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | |
| WATER (UNII: 059QF0K00R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

Product Characteristics

| | | | |
|-----------------|--|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:75556-007-01 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/20/2020 | |



| | |
|--|----------------|
| 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.: 202005126704-1
Net: 236ml

860004037507

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

label size: 5cm x 8cm

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)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|------------------------|
| ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD | | 528198838 | manufacture(75556-007) |

Revised: 5/2020

ZHEJIANG SHUNAN INDUSTRY&TRADE CO.,LTD