

INSTANT 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.

75556-591 59.1 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

to decrease bacteria on the skin, only when water is not available.

Warnings

- Flammable. Keep away from fire and flame.
- For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product . Do not get into eyes. If contact occurs, rinse eyes thoroughly with water. May discolor some fabrics.

Stop use and ask a doctor if

- Irritation or redness develop
- Keep out of reach of children
- If swallowed. get medical help or contact a Poison Control Center right away.

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

Directions

- wet hands thoroughly with product and allow to dry without wiping.

Other information

- Store below 105°

Inactive ingredients

Water, Carbomer, Triethanolamine, Glycerol

Package Label - Principal Display Panel

59.1 mL in 1 Bottle NDC: 75556-591-01

FINELINE

Instant Hand Sanitizer

Drug Facts

Active Ingredient	Purpose
Alcohol 75%.....	Antispetic

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

Directions wet hands thoroughly with product and allow to dry without wiping.

Other information store below 105°F

Inactive Ingredients
Water, Carbomer, Triethanolamine, Glycerol.

NDC: 75556-591-01
Made in China

FINELINE

Instant Hand Sanitizer



Kills 99.99% of Germs

2 FL OZ (59.1 mL)

INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75556-591
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	44.325 mL in 59.1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75556-591-01	59.1 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	

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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
ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD		528198838	manufacture(75556-591)