

HAND SANITIZER- ethyl alcohol gel
ZHEJIANG JINGHUI COSMETICS SHARE 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.

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 70% 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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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

60mL NDC: 73905-014-08



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73905-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYL ACRYLATE (UNII: 705NM8U35V)	
WATER (UNII: 059QF0KO0R)	
DENATONIUM (UNII: 4IK22DF4OU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73905-014-01	2 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:73905-014-02	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:73905-014-03	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:73905-014-04	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:73905-014-05	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:73905-014-06	45 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:73905-014-07	55 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:73905-014-08	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:73905-014-09	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:73905-014-10	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
11	NDC:73905-014-11	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
12	NDC:73905-014-12	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
	NDC:73905-014			

13	NDC:73905-014-13	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
14	NDC:73905-014-14	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
15	NDC:73905-014-15	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
16	NDC:73905-014-16	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
17	NDC:73905-014-17	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
18	NDC:73905-014-18	260 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
19	NDC:73905-014-19	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
20	NDC:73905-014-20	350 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
21	NDC:73905-014-21	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
22	NDC:73905-014-22	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
23	NDC:73905-014-23	560 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
24	NDC:73905-014-24	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
25	NDC:73905-014-25	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
26	NDC:73905-014-26	900 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
27	NDC:73905-014-27	980 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
28	NDC:73905-014-28	985 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
29	NDC:73905-014-29	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
30	NDC:73905-014-30	1300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
31	NDC:73905-014-31	1500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
32	NDC:73905-014-32	1800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
33	NDC:73905-014-33	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
34	NDC:73905-014-34	2500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
35	NDC:73905-014-35	3000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
36	NDC:73905-014-36	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
37	NDC:73905-014-37	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
38	NDC:73905-014-38	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
39	NDC:73905-014-39	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
40	NDC:73905-014-40	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
41	NDC:73905-014-41	25000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
42	NDC:73905-014-42	45000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

43	NDC:73905-014-43	50000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
44	NDC:73905-014-44	100000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
45	NDC:73905-014-45	200000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
46	NDC:73905-014-46	500000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
47	NDC:73905-014-47	1000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - ZHEJIANG JINGHUI COSMETICS SHARE CO.,LTD (529558167)

Establishment

Name	Address	ID/FEI	Business Operations
ZHEJIANG JINGHUI COSMETICS SHARE CO.,LTD		529558167	manufacture(73905-014)

Revised: 5/2020

ZHEJIANG JINGHUI COSMETICS SHARE CO.,LTD