

INSTANT HAND SANITIZER- isopropyl alcohol gel
Jinhua Jinpan Development Zone Shangmei Cosmetics 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. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerine (2.00% v/v).
- c. Aminomethyl Propanediol (0.5% 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)

Isopropyl 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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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

Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

Package Label - Principal Display Panel

50 ml NDC: 78059-001-01

Alcohol Antiseptic 75%
Topical Solution

Hand sterilize gel
Non-sterile Solution

[50 mL]

Drug Facts

Active ingredient(s)

Alcohol 75%V/V.....

Purpose

.....Antiseptic

Use[s]

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Inactive ingredients

Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

60 ml NDC: 78059-001-02

Alcohol Antiseptic 75%

Topical Solution

Hand sterilize gel

Non-sterile Solution

[60 mL]

Drug Facts

Active ingredient(s)

Alcohol 75%V/V.....Antiseptic

Purpose

Use[s]

Hand sterilize gel to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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Other information

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Inactive ingredients Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

100 ml NDC: 78059-001-03

Alcohol Antiseptic 75%

Topical Solution

Hand sterilize gel

Non-sterile Solution

[100 mL]

Drug Facts

Active ingredient(s)

Alcohol 75%V/V.....Antiseptic

Purpose

Use[s]

Hand sterilize gel to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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Inactive ingredients

Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

150 ml NDC: 78059-001-04

Alcohol Antiseptic 75%
Topical Solution

Hand sterilize gel
Non-sterile Solution

[150 mL]

Drug Facts

Active ingredient(s)	Purpose
Alcohol 75%V/V.....	Antiseptic
Use[s]	
Hand sterilize gel 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.	
Directions.	
<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 15-30°C (59-86F)• Avoid freezing and excessive heat above 40°C (104F)	
Inactive ingredients Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance	

250 ml NDC: 78059-001-05

Alcohol Antiseptic 75%
Topical Solution

Hand sterilize gel
Non-sterile Solution

[250 mL]

Drug Facts

Active ingredient(s)

Alcohol 75%V/V.....Antiseptic

Purpose

Use[s]

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Warnings

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Other information

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Inactive ingredients

Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

300 ml NDC: 78059-001-06

Alcohol Antiseptic 75%
Topical Solution

Hand sterilize gel
Non-sterile Solution

[300 mL]

Drug Facts

Active ingredient(s)	Purpose
Alcohol 75%V/V.....	Antiseptic

Use[s]

Hand sterilize gel to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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Other information

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Inactive ingredients Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

500 ml NDC: 78059-001-07

**Alcohol Antiseptic 75%
Topical Solution**

**Hand sterilize gel
Non-sterile Solution**

[500 mL]

Drug Facts

Active ingredient(s)

Alcohol 75%V/V.....Antiseptic

Purpose

Use[s]

Hand sterilize gel to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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Other information

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Inactive ingredients

Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

1000 ml NDC: 78059-001-08

Alcohol Antiseptic 75%**Topical Solution****Hand sterilize gel****Non-sterile Solution**

[1000 mL]

Drug Facts**Active ingredient(s)**

Alcohol 75%V/V.....Antiseptic

Purpose**Use[s]**

Hand sterilize gel to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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- Avoid freezing and excessive heat above 40°C (104F)

Inactive ingredients

Ethyl Alcohol Aqua Modified acrylic polymer Glycerine Aminomethyl propanol Fragrance

INSTANT HAND SANITIZER

isopropyl alcohol gel

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:78059-001

Route of Administration

TOPICAL

Active Ingredient/Active Moiety**Ingredient Name****Basis of Strength****Strength**

ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	21.85 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78059-001-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
2	NDC:78059-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
3	NDC:78059-001-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
4	NDC:78059-001-04	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
5	NDC:78059-001-05	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
6	NDC:78059-001-06	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
7	NDC:78059-001-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	
8	NDC:78059-001-08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	06/04/2020	

Labeler - Jinhua Jinpan Development Zone Shangmei Cosmetics Co.,Ltd (542997968)

Registrant - Jinhua Jinpan Development Zone Shangmei Cosmetics Co.,Ltd (542997968)

Establishment

Name	Address	ID/FEI	Business Operations
Jinhua Jinpan Development Zone Shangmei Cosmetics Co.,Ltd		542997968	manufacture(78059-001)

Revised: 6/2020

Jinhua Jinpan Development Zone Shangmei Cosmetics Co.,Ltd