

HAND SANITIZER- isopropyl alcohol gel
Jiangxi Chief Industrial 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.

Hand Sanitizer-Chief

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. 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)

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.

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 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

60 ml NDC: 75524-002-01

|  HAND SANITIZER WITH MOISTURIZERS KILLS 99.99% OF GERMS 2 FL OZ / 60mL | DRUG FACTS | | | |
|--|--|-------------------|---------|-------------------|
| | <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Ethyl Alcohol 75%</td><td>Antiseptic</td></tr></tbody></table> <p>Use[s] Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p> <p>Warnings For external use only. Flammable. Keep away from heat or flame</p> <p>Do not use • In children less than 2 months of age. • On open skin wounds.</p> <p>When using this product Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p> <p>OTC - Stop use and ask a doctor If irritation or rash occurs. These may be signs of serious conditions.</p> <p>OTC - Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Other information • Store between 15°C-30°C (59°F-86°F) • Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive ingredients Distilled and deionized water, Glycerin, Carbomer, Triethanolamine</p> | Active ingredient | Purpose | Ethyl Alcohol 75% |
| Active ingredient | Purpose | | | |
| Ethyl Alcohol 75% | Antiseptic | | | |
| Manufacturer: Jiangxi Chief Industrial Co., Ltd. No. 1866 Chief Industrial Park, Dongsheng Avenue, Nanchang City, Jiangxi Province, China 330012 Product Number: EXP Date: On the bottle Made in China |  6 958505 908250 | | | |

100 ml NDC: 75524-002-02



HAND SANITIZER

75% ETHANOL
WITH MOISTURIZERS

KILLS 99.99% OF GERMS



3.52 fl oz / 100ml

DRUG FACTS

Active ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Use[s]

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.

OTC - Stop use and ask a doctor

If irritation or rash occurs. These may be signs of serious conditions.

OTC - 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

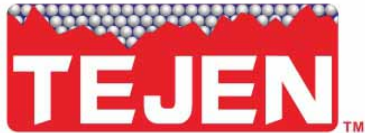
- Store between 15°C-30°C (59°F-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Distilled and deionized water, Glycerin, Carbomer, Triethanolamine

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012
Product Number: EXP Date: On the bottle
Made in China

236 ml NDC: 75524-002-03



HAND SANITIZER

WITH MOISTURIZERS

KILLS 99.99% OF GERMS

8 FL OZ (236 ml)

DRUG FACTS

| Active ingredient | Purpose |
|-------------------|------------|
| Ethyl Alcohol 75% | Antiseptic |

Use[s]
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.

OTC - Stop use and ask a doctor
If irritation or rash occurs. These may be signs of serious conditions.

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

Inactive ingredients
Distilled and deionized water, Glycerin, Carbomer, Triethanolamine

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012
Product Number: EXP Date: On the bottle
Made in China



300 ml NDC: 75524-002-04

DRUG FACTS

| Active ingredient | Purpose |
|-------------------|------------|
| Ethyl Alcohol 75% | Antiseptic |

Use[s]
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.

OTC - Stop use and ask a doctor
If irritation or rash occurs. These may be signs of serious conditions.

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



HAND SANITIZER
75% ETHYL ALCOHOL
WITH MOISTURIZERS
KILLS 99.99% OF GERMS

10.15 fl oz / 300ml



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

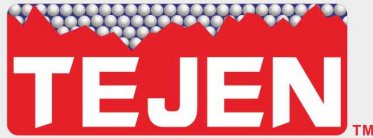
Inactive ingredients

Distilled and deionized water, Glycerin, Carbomer, Triethanolamine

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012

Made in China
Product Number:
EXP Date: On the bottle

450 ml NDC: 75524-002-05



HAND SANITIZER

**75% ETHANOL
WITH MOISTURIZERS**

KILLS 99.99% OF GERMS



15.2 fl oz / 450ml

DRUG FACTS

| Active ingredient | Purpose |
|-------------------|------------|
| Ethyl Alcohol 75% | Antiseptic |

Use[s]
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.

OTC - Stop use and ask a doctor
If irritation or rash occurs. These may be signs of serious conditions.

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

Inactive ingredients
Distilled and deionized water, Glycerin, Carbomer, Triethanolamine

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012
Product Number:
EXP Date: On the bottle
Made in China

500 ml NDC: 75524-002-06

| DRUG FACTS | |
|--|------------------------------|
| Active ingredient Ethyl Alcohol 75% | Purpose Antiseptic |
| Use[s] 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. | |
| OTC - Stop use and ask a doctor If irritation or rash occurs. These may be signs of serious conditions. | |
| OTC - Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away. | |



HAND SANITIZER
75% ETHYL ALCOHOL
WITH MOISTURIZERS
KILLS 99.99% OF GERMS

16.9 fl oz / 500ml

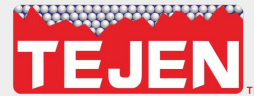


| |
|---|
| Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. |
| Other information • Store between 15°C-30°C (59°F-86°F) • Avoid freezing and excessive heat above 40°C (104°F) |
| Inactive ingredients Distilled and deionized water, Glycerin, Carbomer, Triethanolamine |

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012
Product Number:
EXP Date: On the bottle

Made in China

1L NDC: 75524-002-07



HAND SANITIZER

— 75% ETHANOL —



WITH MOISTURIZERS
KILLS 99.99% OF GERMS

33.8 fl oz / 1L

DRUG FACTS

| Active ingredient | Purpose |
|-------------------|------------|
| Ethyl Alcohol 75% | Antiseptic |

Use[s]

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.

OTC - Stop use and ask a doctor

If irritation or rash occurs. These may be signs of serious conditions.

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

Inactive ingredients

Distilled and deionized water, Glycerin, Carbomer, Triethanolamine

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012
Product Number:
EXP Date: On the bottle
Made in China

2L NDC: 75524-002-08



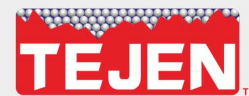
HAND SANITIZER

— 75% ETHANOL —



WITH MOISTURIZERS
KILLS 99.99% OF GERMS

67.6 fl oz / 2L



DRUG FACTS

| Active ingredient | Purpose |
|-------------------|------------|
| Ethyl Alcohol 75% | Antiseptic |

Use[s]

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

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Distilled and deionized water, Glycerin, Carbomer, Triethanolamine

Manufacturer: Jiangxi Chief Industrial Co., Ltd.
No. 1866 Chief Industrial Park, Dongsheng Avenue,
Nanchang City, Jiangxi Province, China 330012
Product Number:
EXP Date: On the bottle
Made in China

HAND SANITIZER

isopropyl alcohol gel

Product Information

| | | | | |
|--|---|---|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75524-002 | |
| 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 | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | 1.45 mL in 100 mL | | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | | 0.125 mL in 100 mL | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:75524-002-01 | 60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 2 | NDC:75524-002-02 | 100 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 3 | NDC:75524-002-03 | 236 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 4 | NDC:75524-002-04 | 300 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 5 | NDC:75524-002-05 | 450 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 6 | NDC:75524-002-06 | 500 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 7 | NDC:75524-002-07 | 1000 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| 8 | NDC:75524-002-08 | 2000 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/30/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333A | 04/30/2020 | | |

Labeler - Jiangxi Chief Industrial Co., Ltd. (544328452)

Registrant - Jiangxi Chief Industrial Co., Ltd. (544328452)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------------|---------|-----------|------------------------|
| Jiangxi Chief Industrial Co., Ltd. | | 544328452 | manufacture(75524-002) |

