

BACTERIOSTATIC STERILIZING GEL- alcohol liquid

Jilin Zhengde Pharmaceutical 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) (78%, 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. 1,2-propanediol
- c. GLYCEROL
- d. Carbomer
- e. Jojoba oil
- f. 2-Amino-2-methyl-propanol
- g. 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 78% 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

WATER

1,2-propanediol

GLYCEROL

Carbomer

Jojoba oil

2-Amino-2-methyl-propanol

Package Label - Principal Display Panel

28 mL NDC: 74450-001-01

60 mL NDC: 74450-002-01

180 mL NDC: 74450-003-01

300 mL NDC: 74450-004-01

500 mL NDC: 74450-005-01

正嘉[®]

免洗净手
消毒凝胶



- | | |
|--|--|
| <input checked="" type="checkbox"/> 护肤 | <input checked="" type="checkbox"/> 消毒 |
| <input checked="" type="checkbox"/> 速干 | <input checked="" type="checkbox"/> 保湿 |

净含量：28ml

正嘉®

免洗净手消毒凝胶

BACTERIOSTATIC STERILIZING GEL



速干型

60ml



正嘉®

免洗净手消毒凝胶
BACTERIOSTATIC STERILIZING GEL



速干型

180ML





正嘉®

免洗净手消毒凝胶
BACTERIOSTATIC STERILIZING GEL

速干型



500ml

BACTERIOSTATIC STERILIZING GEL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74450-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.78 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74450-005-01	500 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	

BACTERIOSTATIC STERILIZING GEL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74450-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.78 mL in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
JOJOBA OIL (UNII: 724GKU717M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74450-001-01	28 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	

BACTERIOSTATIC STERILIZING GEL				
alcohol liquid				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:74450-002
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	0.78 mL in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
JOJOBA OIL (UNII: 724GKU717M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:74450-002-01	60 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	

BACTERIOSTATIC STERILIZING GEL

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74450-003	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	0.78 mL in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
JOJOBA OIL (UNII: 724GKU717M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74450-003-01	180 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	

BACTERIOSTATIC STERILIZING GEL

alcohol liquid

Product Information				
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Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:74450-004
Route of Administration		TOPICAL			
Active Ingredient/Active Moiety					
Ingredient Name			Basis of Strength		Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL		0.78 mL in 1 mL
Inactive Ingredients					
Ingredient Name				Strength	
JOJOBA OIL (UNII: 724GKU717M)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
CARBOMER 940 (UNII: 4Q93RCW27E)					
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)					
GLYCERIN (UNII: PDC6A3C0OX)					
WATER (UNII: 059QF0KO0R)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74450-004-01	300 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 - Jilin Zhengde Pharmaceutical Co., Ltd. (421125060)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jilin Zhengde Pharmaceutical Co., Ltd.		421125060	manufacture(74450-001, 74450-002, 74450-003, 74450-004, 74450-005)	