

STANDARD- disinfection gel gel
Guangzhou Ouzhuang Biological Technology 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.

Guangzhou-STANDARD GEL

Active Ingredient(s)

Alcohol 73% 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

propylene glycol, carbomer, triethanolamine, purified water

Package Label - Principal Display Panel

<p>DISINFECTION GEL kills over 99.99% of germs</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">State: gel;</td> </tr> <tr> <td style="padding: 2px;">Action: effectively kills 99.99% of pyogenic bacteria, enteropathogenic bacteria and pathogenic yeast (under testing environment);</td> </tr> <tr> <td style="padding: 2px;">Usage: squeeze on to skin of hand and rub for 2 minutes;</td> </tr> <tr> <td style="padding: 2px;">Precautions: seal and place in a cool and dry place.</td> </tr> </table> <p>QC Inspection: Pass Period of validity: 2 years Production batch number and expiration date (YYMMDD) as indicated Made in China</p>	State: gel;	Action: effectively kills 99.99% of pyogenic bacteria, enteropathogenic bacteria and pathogenic yeast (under testing environment);	Usage: squeeze on to skin of hand and rub for 2 minutes;	Precautions: seal and place in a cool and dry place.	<p>STANDARD Hand Sanitizer</p> <p>Kills 99.9% Germs 73% Alcohol</p>  <p>500 ml / 16.9 FL.OZ</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th style="text-align: left;">Active Ingredient</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Alcohol 73%</td> <td>Antiseptic</td> </tr> <tr> <th colspan="2">Use(s)</th> </tr> <tr> <td colspan="2">Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <th colspan="2">Warnings</th> </tr> <tr> <td colspan="2">For external use only. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2">• in children less than 2 months of age</td> </tr> <tr> <td colspan="2">• on open skin wounds</td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. There may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <th colspan="2">Directions</th> </tr> <tr> <td colspan="2">• Place enough product on hands to cover all surfaces. Rub hands together until dry.</td> </tr> <tr> <td colspan="2">• Supervise children under 6 of age when using this product to avoid swallowing.</td> </tr> <tr> <th colspan="2">Other information</th> </tr> <tr> <td colspan="2">• Store between 15-30°C (59-86°F).</td> </tr> <tr> <td colspan="2">• Avoid freezing and excessive heat above 40°C (104°F).</td> </tr> <tr> <th colspan="2">Inactive Ingredients</th> </tr> <tr> <td colspan="2">propylene glycol, carbomer, triethanolamine, purified water</td> </tr> </table>	Drug Facts		Active Ingredient	Purpose	Alcohol 73%	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. 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. There 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 of age when using this product to avoid swallowing.		Other information		• Store between 15-30°C (59-86°F).		• Avoid freezing and excessive heat above 40°C (104°F).		Inactive Ingredients		propylene glycol, carbomer, triethanolamine, purified water	
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500 mL NDC: 77598-124-04

STANDARD				
disinfection gel gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77598-124	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL	
Inactive Ingredients				
	Ingredient Name		Strength	
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
	WATER (UNII: 059QF0K00R)			
	TROLAMINE (UNII: 9O3K93S3TK)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77598-124-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
2	NDC:77598-124-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:77598-124-03	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:77598-124-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
5	NDC:77598-124-05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
6	NDC:77598-124-06	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2020	

Labeler - Guangzhou Ouzhuang Biological Technology Co Ltd (418234821)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Ouzhuang Biological Technology Co Ltd		418234821	manufacture(77598-124)

Revised: 5/2020

Guangzhou Ouzhuang Biological Technology Co Ltd