

HEALPEACE- disinfection gel gel

HealPeace

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

Alcohol 73% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

For external use only. Flammable. Keep away from heat or flame

- 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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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.

Store between 15-30C (59-86F)

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

propylene glycol, carbomer, triethanolamine, purified water

Package Label - Principal Display Panel

300 mL NDC: 75530-123-02

<p>DISINFECTION GEL kills over 99.99% of germs</p> <p>State: gel;</p> <p>Action: effectively kills 99.99% of pyogenic bacteria, enteropathogenic bacteria and pathogenic yeast (under testing environment);</p> <p>Usage: squeeze on to skin of hand and rub for 2 minutes;</p> <p>Precautions: seal and place in a cool and dry place.</p> 	 <p>HAND SANITIZER</p> <p>kills 99.99% of germs 73% Ethyl Alcohol</p> <p>10FL OZ(300ML)</p>	<table border="1"> <tr> <td>Drug Facts</td> <td>Purpose</td> </tr> <tr> <td>Active Ingredient Alcohol 73%</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Uses Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <td colspan="2">Warnings 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. These 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> <td colspan="2">Directions</td> </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> <td colspan="2">Other information</td> </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> <td colspan="2">Inactive Ingredients propylene glycol, carbomer, triethanolamine, purified water</td> </tr> </table>	Drug Facts	Purpose	Active Ingredient Alcohol 73%	Antiseptic	Uses 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. 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 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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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75530-123
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
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75530-123-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
2	NDC:75530-123-02	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	
3	NDC:75530-123-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/28/2020	

Labeler - HealPeace (117488461)**Establishment**

Name	Address	ID/FEI	Business Operations
HealPeace		117488461	label(75530-123)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Ouzhuang Biological Technology Co Ltd		418234821	manufacture(75530-123)