

INSTANT HAND ANTISEPTIC- benzalkonium chloride gel
ASP Global, LLC

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.

Instant Hand Antiseptic

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.095%

Purpose

Antiseptic

Uses

To help reduce bacteria on hands.

Warnings

For external use only.

When using this product avoid contact with eyes and lips. If contact occurs, rinse with water.

Stop use and ask a doctor if irritation or redness develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Rub dime sized amount between hands until dry.

Children under 6 years of age should be supervised when using this product.

Inactive Ingredients

Glycerin, Methylisothiazolinone, Propylene Glycol, Polyquaternium-37, Triethanolamine.
Water

Distributed by :

ASP Global, LLC
7800 Third Flag Parkway,

Austell, GA 30168, USA

PRINCIPAL DISPLAY PANEL - 53 mL Bottle Label

ENGLEWOOD
HEALTH

Instant Hand Antiseptic

Alcohol & Fragrance Free

1.9 FL OZ / 53 mL

Distributed by :
ASP Global, LLC
7800 Third Flag Parkway,
Austell, GA 30168, USA

Rev 03

 <p>ENGLEWOOD HEALTH</p> <p>Instant Hand Antiseptic Alcohol & Fragrance Free</p> <p>1.9 FL OZ / 53 mL</p> <p>Distributed by : ASP Global, LLC 7800 Third Flag Parkway, Austell, GA 30168, USA</p> <p>Rev 03</p>	<p>Drug Facts</p> <table><tr><td>Active Ingredient</td><td>Propose</td></tr><tr><td>Benzalkonium Chloride 0,095%</td><td>Antiseptic</td></tr></table> <p>Uses</p> <p>To help reduce bacteria on hands.</p> <p>Warnings</p> <p>For external use only. When using this product avoid contact with eyes and lips. If contact occurs, rinse with water. Stop use and ask a doctor if irritation or redness develops. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions</p> <p>Rub dime sized amount between hands until dry. Children under 6 years of age should be supervised when using this product.</p> <p>Inactive Ingredients</p> <p>Glycerin, Methylisothiazolinone, Propylene Glycol, Polyquaternium-37, Triethanolamine, Water</p> <p>Made in China</p>	Active Ingredient	Propose	Benzalkonium Chloride 0,095%	Antiseptic
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Benzalkonium Chloride 0,095%	Antiseptic				

INSTANT HAND ANTISEPTIC

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59448-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	0.095 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
POLYQUATERNIUM-37 (25000 MPA.S) (UNII: 31L31U8285)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Methylisothiazolinone (UNII: 229D0E1QFA)	
Trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59448-002-01	53 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/01/2018	

Labeler - ASP Global, LLC (080361159)

Establishment

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	MANUFACTURE(59448-002)

