# 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.

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### **Instant Hand Antiseptic**

## **Drug Facts**

# **Active Ingredient**

Benzalkonium Chloride 0.095%

# **Propose**

**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

ASP MEDICAL

**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 01



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Made in China

# benzalkonium chloride gel

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59448-003

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ш	Active mg. calend, terror locely				
	Ingredient Name	Basis of Strength	Strength		
	<b>Benzalkonium Chloride</b> (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: 903K93S3TK)			

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:59448- 003-01	53 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/27/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	11/27/2018		

# Labeler - ASP Global, LLc (080361159)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Nantong Health & Beyond Hygienic Products Inc.		421280161	MANUFACTURE(59448-003)		

Revised: 12/2021 ASP Global, LLc