# ANTIBACTERIAL HAND SANITIZER- benzalkonium chloride gel Aogrand International Trade Corporation

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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#### **Antibacterial Hand Sanitizer**

### **Active Ingredient(s)**

Benzalkonium Chloride 0.1%. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

#### Use

- hand Sannitizer to help decrease bacteria on the skin, when water, soap & towel are not available.
- recommended for repeated use

# Warnings

For external use only.

Do not apply around eyes. Do not use in ears & mouth.

# When using this product

avoid contact with eyes. In case of contact, flush eyes with water.

# Stop use and ask a doctor

if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

#### **Directions**

- Place enough product into your palms and thoroughly spread on both hands
- rub into skin until dry

# **Inactive ingredients**

Cocamidopropylamine oxide, C12-20 Alkyl glycoside, glycerin, hydroxyethyl cellulose,

Casone (methylisothiazolinone and methylchloroisothiazolinone), citric acid, deionized water

### Other information

• store below 110F (43C)

• may discolor certain fabrics or surfaces

# **Package Label - Principal Display Panel**

1180ml NDC: 74621-007-01



1500ml NDC: 74621-007-02



# **ANTIBACTERIAL HAND SANITIZER**

benzalkonium chloride gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74621-007	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL		

Inactive Ingredients		
	Ingredient Name	Strength

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)	
WATER (UNII: 059QF0KO0R)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:74621- 007-01	1180 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2020		
2	NDC:74621- 007-02	1500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/23/2020	

# **Labeler -** Aogrand International Trade Corporation (421353092)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Aogrand International Trade Corporation		421353092	manufacture(74621-007)	

Revised: 2/2023 Aogrand International Trade Corporation