# OLJE ANTIBACTERIAL WIPES- benzalkonium chloride swab AJ 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.

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### AJ Co., Ltd. - Olje Antibacterial Wipes

Benzalkonium Chloride

water, propylene glycol, phenoxyethanol, glycerin, sodium benzoate, sodium citrate, disodium edta, polysorbate 20, citric acid, melaleuca alternifolia (tea tree) leaf oil, tocopheryl acetate

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

keep out of reach of the children

Thoroughly wipe hands with wipe.

Discard properly. Not flushable.

Be sure to close lid to keep wipes moist.

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 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.

for external use only

## Drug Facts

## Active Ingredient

Purpose

Benzalkonium Chloride 0.1% ------ Antibacterial

#### Uses

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

### Warnings

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

#### Directions

- Thoroughly wipe hands with wipe.
- Discard properly. Not flushable.
- Be sure to close lid to keep wipes moist.

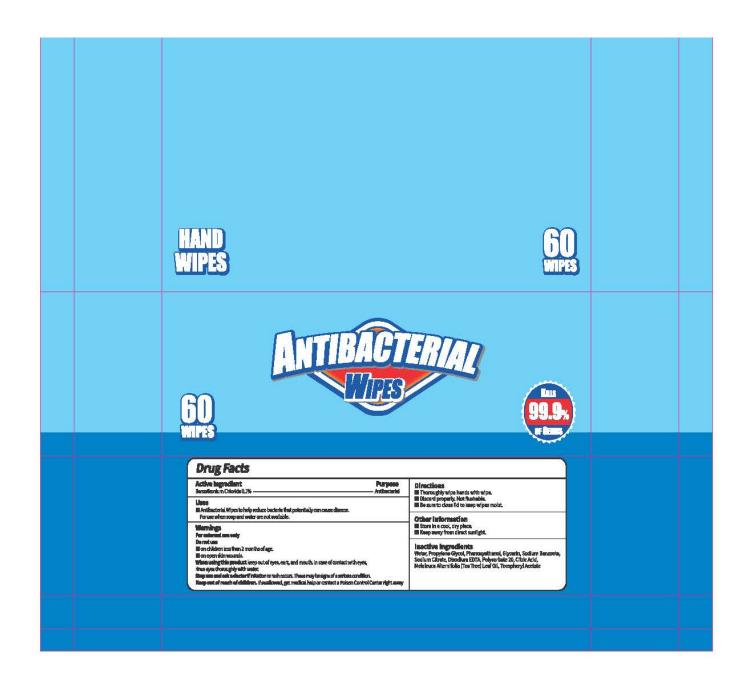
#### Other Information

- Store in a cool, dry place
- Keep away from direct sunlight

### Inactive Ingredients

Water, Propylene Glycol, Phenoxyethanol, Glycerin, Sodium Benzoate, Sodium Citrate, Disodium EDTA, Polysorbate 20, Citric Acid, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopheryl Acetate





## **OLJE ANTIBACTERIAL WIPES**

benzalkonium chloride swab

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75356-0006
Route of Administration	TOPICAL		
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Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	0.4 g in 407 g	

Inactive Ingredients			
Ingredient Name	Strength		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
TEA TREE OIL (UNII: VIF565UC2G)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
GLYCERIN (UNII: PDC6A3C0OX)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
WATER (UNII: 059QF0KO0R)			

ı	Packaging			
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75356- 0006-1	407 g in 1 PACKET; Type 0: Not a Combination Product	01/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2021	

## **Labeler -** AJ Co., Ltd. (631079605)

## **Registrant -** AJ Co., Ltd. (631079605)

Establishment			
Name	Address	ID/FEI	Business Operations
AJ Co., Ltd.		631079605	manufacture(75356-0006) , label(75356-0006) , pack(75356-0006)

Revised: 3/2021 AJ Co., Ltd.