## ANTIBACTERIAL HAND WIPES- wipes cloth Osike Cosmetics 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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#### 79866-008

#### **Antibacterial Hand Wipes**

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

Benzalkonium Chloride 0.13%

#### **Purpose**

#### Use

- Hand sanitizer to help reduce bacteria
- •For use when soap and water are not available.

#### **Warnings**

For external use only.

Do not use

- •in children less than 2 months old.
- 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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#### **Directions**

- Apply to hands, allow to air dry without wiping.
- ●Children under 6 years of age should be supervised when using this product

#### Other information

- •Store in a cool, dry place.
- •Avoid freezing and excessive heat.

#### **Inactive ingredients**

Aloe Barbadensis Extract, Alpha-Tocopherol, Fragrance, Glycerin, Phenoxyethanol, Propylene Glycol, Purified Water

#### Package Label - Principal Display Panel



#### 315mm

# ANTIBACTERIAL HAND WIPES wipes cloth Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:79866-008

#### Route of Administration

TOPICAL

<b>Active</b>	Ingredient/Active	Moiety
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Active ingredient/Active Molety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	0.13 g in 100	

Inactive Ingredients		
Ingredient Name	Strength	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)		
GLYCERIN (UNII: PDC6A3C0OX)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:79866-008- 01	75 in 1 DRUM; Type 0: Not a Combination Product	09/16/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/16/2020	

### Labeler - Osike Cosmetics Co., Ltd. (415803943)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Osike Cosmetics Co., Ltd.		415803943	manufacture(79866-008)	

Revised: 1/2022 Osike Cosmetics Co., Ltd.