

WET WIPE- wet 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.

79866-010
WET WIPE

Active Ingredient(s)

Benzalkonium Chloride 0.13%Antimicroblal

Purpose

Antimicroblal

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

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.

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, between 15°C-30°C [59°F-86°F]
- Avoid freezing and excessive heat above 40°C [104°F]

Inactive ingredients

Aloe Barbadosis Extract, Alpha-Tocopherol, Fragrance, Glycerin,

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79866-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 in 100

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79866-010-01	40 in 1 DRUM; Type 0: Not a Combination Product	12/07/2020	
2	NDC:79866-010-02	75 in 1 DRUM; Type 0: Not a Combination Product	12/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/07/2020	

Labeler - Osike Cosmetics Co., Ltd. (415803943)**Establishment**

Name	Address	ID/FEI	Business Operations
Osike Cosmetics Co., Ltd.		415803943	manufacture(79866-010)

Revised: 12/2020

Osike Cosmetics Co., Ltd.