

ULTRACLEAN ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth
Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi

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.

UltraClean® ANTIBACTERIAL WET WIPES

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose

Antimicrobial

Uses

Hand sanitizer wipes to help reduce bacteria and germs on the skin.

Recommended for repeated use.

Warnings

For external use only

When using this product Avoid contacting with eyes. In case of eye contact, rinse eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children If swallowed, get medical help or contact a poison control center right away.

Directions

- Take wipe and rub thoroughly over all surfaces of both hands. Wet hands thoroughly with wipe and allow to dry, discard after use.
- Children under 6 years of age should be supervised when using this product.

Other information

Store at room temperature. Keep tightly closed when not in use.

Dispose of used wipe in trash. Do not flush.

Inactive ingredients

Water (Aqua), Phenoxyethanol, Peg 7 glyceryl cocoate, Polysorbate 20, Glycerin, Lime oil, Cocamidopropyl betaine, Citric acid, Limonene, Hexyl Cinnamal, Citral, Citronellol, Geraniol, Benzyl Benzoate, Linalool.

PLUS FORMULA

PROTECTION

instant effect!

Free of Paraben, Dye and Phthalates

SANITIZING WIPES

5.70 IN X 8.26 IN (14.5cm x 21cm)

FOR HAND SANITIZING TO DECREASE BACTERIA AND GERMS ON THE SKIN

• Sanitizing formula to help reduce cross-contamination and risk of infection.

• Leaves no stickiness or residue on hands.

• Hands feel smooth, soft and refreshed.

To Open Package:

• Flip open dispensing lid

• Locate wipe at center of roll and thread through small opening in lid

• For best results dispense wipes at an angle

• Always close lid securely between uses to retain moisture

TO DISPOSE WIPE: Place in a waste basket after use.

DO NOT FLUSH

16.29 OZ. (462 g) ± 5%

Distributed by

Civilon LLC

Clifton, NJ, 07011

MADE IN TURKEY

OZONE FRIENDLY

Packaging

<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Benzalkonium Chloride 0.13%</td><td>Antimicrobial</td></tr></tbody></table> <p>Uses Hand sanitizer wipes to help reduce bacteria and germs on the skin. Recommended for repeated use.</p> <p>Warnings For external use only</p> <p>When using this product avoid contacting with eyes. In case of eye contact, rinse eyes with water.</p> <p>Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.</p> <p>Keep out of reach of children if swallowed, get medical help or contact a poison control center right away.</p> <p>Directions • Take wipe and rub thoroughly over all surfaces of both hands. Wet hands thoroughly with wipe and allow to dry, discard after use. • Children under 6 years of age should be supervised when using this product.</p> <p>Other information Store at room temperature. Keep tightly closed when not use. Dispose of used wipe in trash. Do not flush.</p> <p>Inactive Ingredients Water (Aqua), Phenoxyethanol, Peg 7 glyceryl cocoate, Polysorbate 20, Glycerin, Lime oil, Cocamidopropyl betaine, Citric acid, Limonene, Hexyl Cinnamal, Citral, Citronellol, Geraniol, Benzyl Benzoate, Linalool.</p>	Active Ingredient	Purpose	Benzalkonium Chloride 0.13%	Antimicrobial	 <p>instant effect!</p>  <p>SANITIZER ANTIBACTERIAL WET WIPES</p> <p>FOR HAND SANITIZING TO DECREASE BACTERIA AND GERMS ON THE SKIN</p> <p>ANTIBACTERIAL WET WIPES</p> <p>Free of Paraben, Dye and Phthalates</p> <p>72 SANITIZING WIPES 5.70 IN X 8.26 IN (14.5cm x 21cm)</p>	<p>SANITIZER ANTIBACTERIAL WET WIPES</p> <p>FOR HAND SANITIZING TO DECREASE BACTERIA AND GERMS ON THE SKIN</p> <ul style="list-style-type: none">• Sanitizing formula to help reduce cross-contamination and risk of infection.• Leaves no stickiness or residue on hands.• Hands feel smooth, soft and refreshed. <p>To Open Package:</p> <ul style="list-style-type: none">• Flip open dispensing lid• Locate wipe at center of roll and thread through small opening in lid• For best results dispense wipes at an angle• Always close lid securely between uses to retain moisture  <p>8 68073 14247 4</p> <p>TO DISPOSE WIPE: Place in a waste basket after use. DO NOT FLUSH</p>  <p>16.29 OZ. (462 g) ± 5%</p>
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DRUG FACTS TABLE

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ULTRACLEAN ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78089-030
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 g in 100 g

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
GLYCERIN (UNII: PDC6A3C0OX)
LIME OIL (UNII: UZH29XGA8G)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
CITRAL (UNII: T7EU0O9VPP)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837108USY)
BENZYL BENZOATE (UNII: N863NB338G)
LINALOOL, (+/-)- (UNII: D81QY6I88E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78089-030-01	72 in 1 PACKET	07/24/2020	
1		4.11 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:78089-030-02	72 in 1 PACKET	07/24/2020	
2		3.64 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/24/2020	

Labeler - Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi (565678914)

Establishment

Name	Address	ID/FEI	Business Operations
Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi		565678914	manufacture(78089-030)

Revised: 7/2020

Endeks Kimya Sanayi Ve Ticaret Anonim Sirketi