

## **ULTRACLEAN- sanitizer wet wipes swab**

### **SIRIUS ENDUSTRI YATIRIMLARI VE PLASTIK SANAYI 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.*

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## **SIRIUS-UltrClean Wet Wipes**

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

Benzalkonium chloride 0.115%

### **Purpose**

Antiseptic

### **Use**

For sanitizing to help reduce bacteria on the skin. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame.

Not edible, don't drink. Do not use in ears or mouth.

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**

Wet hands thoroughly with the product and allow it to dry, discard after use.

Children under 6 years of age should be supervised when using UltraClean Products.

### **Other information**

- Avoid excessive heat or freezing. Store between 15-30 C.
- Dispose the used wipe in trash, do not flush it into the toilet.
- The product may discolor certain fabrics or surfaces.

### **Inactive ingredients**

Water, citric acid, lime oil, Cocamidopropyl betaine, Phenoxyethanol, Polysorbate 20, peg-7 glyceryl cocoate

Package Label - Principal Display Panel

Distributed by  
**Civilon LLC**  
 229 Crooks Ave. #363  
 Clifton, NJ, 07011



MADE IN TURKEY

KILLS 99.9% OF ILLNESS CAUSING GERMS

**SANITIZER**  
 ANTIBACTERIAL WET WIPES

**72**  
 SANITIZING  
 WIPES



Free of Paraben, Dye and Phthalates



**SANITIZER**  
 ANTIBACTERIAL WET WIPES

**Drug Facts**

<p><b>Active Ingredient</b>                  Purpose                  Benzalkonium Chloride 0.119% w/v ..... Antiseptic</p>	<p><b>Directions</b>                  * Wet hands thoroughly with product and allow to dry, discard after use                  * Children under 6 years of age should be supervised when using ULTRACLEAN products</p>
<p><b>Uses</b>                  For sanitizing to help reduce bacteria on the skin. For use when soap and water are not available</p>	<p><b>Other Information</b>                  Avoid excessive heat or freezing. Store between 15-30C. Dispose of used wipe in trash, do not flush into toilet. This product may discolor certain fabrics or surfaces.</p>
<p><b>Warnings</b>                  For external use only.                  When using this product avoid contacting with eyes. In case of eye contact, rinse eyes with water.                  Stop use and seek a doctor if irritation or redness appears and lasts.                  Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.</p>	<p><b>Inactive Ingredients</b> Citric Acid, Cocamidopropyl Betaine, Lime (Citrus) Oil, Phenylethanol(3), Polysorbate 20, Peg 7 Glyceryl Cocoate, Water (Aqua)</p>



330.00 mm

# ULTRACLEAN

sanitizer wet wipes swab

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77222-224
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.115 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LIME OIL (UNII: UZH29XGA8G)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77222-224-01	72 in 1 PACKAGE	06/20/2020	
1		100 mL in 1 NOT APPLICABLE; 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	06/20/2020	

**Labeler** - SIRIUS ENDUSTRI YATIRIMLARI VE PLASTIK SANAYI ANONIM SIRKETI (520078677)

## Establishment

Name	Address	ID/FEI	Business Operations
SIRIUS ENDUSTRI YATIRIMLARI VE PLASTIK SANAYI ANONIM SIRKETI		520078677	manufacture(77222-224)