

## **ZETOX ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth SCK ZETA DIS TICARET**

*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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### **Zetox Antibacterial Wet Wipes**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Benzalkonium Chloride 0.2 % ( w/w )
- b. Glycerin
- c. Phenoxyethanol
- d. Water
- e. Benzoic Acid
- f. Etidronate Tetrasodium
- g. Peg-7 Glyceryl Cocoate
- h. Polysorbate 20
- i. Melaleuca Alternifolia Leaf
- j. Ethylhexylglycerin
- k. Cocamidopropyl Betaine
- l. Anhydrous Citric Acid
- m. Dehydroacetic Acid The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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

Benzalkonium Chloride 0.2% w/w. Purpose: Antibacterial

### **Purpose**

Antiseptic, Antibacterial, Hand Sanitizer

### **Use**

It is an ideal product that provides fast cleaning for your skin with its ready-to-use structure. You can easily use it at home, outside, in car and during travel. User group personal and general use.

### **Warnings**

For external use only.

Before using, certainly read the label and the instructions.

## Do not use

- on open skin wounds

When using this product Keep out of reach of children, food and animal feeds. Do not eat, drink and smoking. Follow use instructions to prevent risks on human and environmental health. If contact the skin: This product is produced to contact the skin. Wash the excess with water. In case of redness, swelling, itching or burning occurs, get medical help. In case of eye contact: wash the eyes with the clean water at least 15 minutes with the eyes cover open. If swallowed shake the mouth with water. Do not induce vomiting. Immediately apply to the doctor and show him the label of the product.

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

- use wipes as much as needed, used by wiping the hands, between the fingers, all internal and external surfaces, and under the nails. Do not rinse after use.

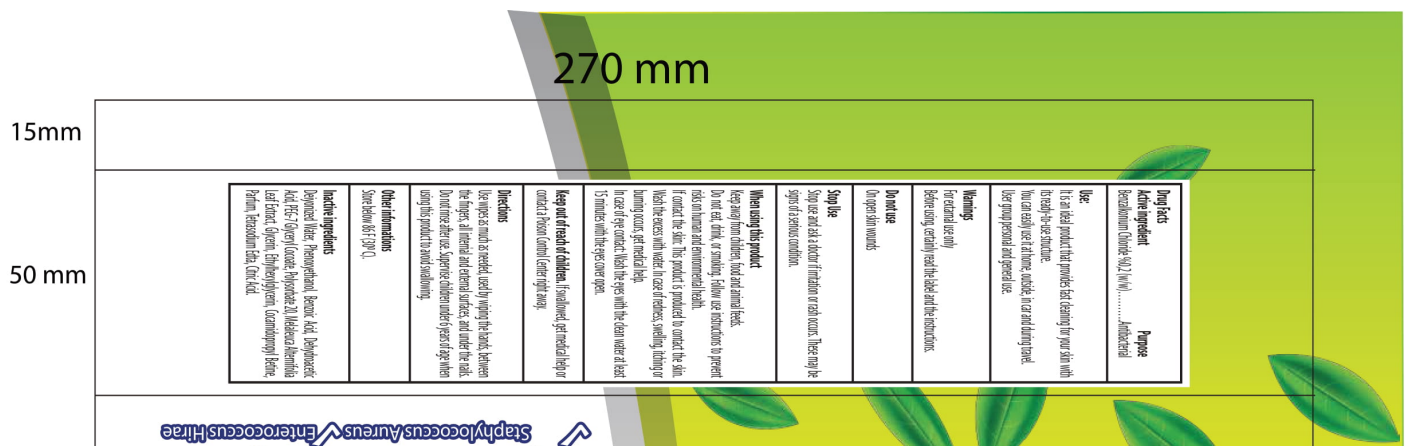
## Other information

Store below 30C (86F)

## Inactive ingredients

Glycerin, Phenoxyethanol, Water, Benzoic Acid, Tetrasodium EDTA, Peg-7 Glyceryl Cocoate, Polysorbate 20, Melaleuca Alternifolia Leaf Extract, Parfum, Ethylhexylglycerin, Cocamidopropyl Betaine, Citric Acid, Dehydroacetic Acid

## Package Label - Principal Display Panel



96 mm

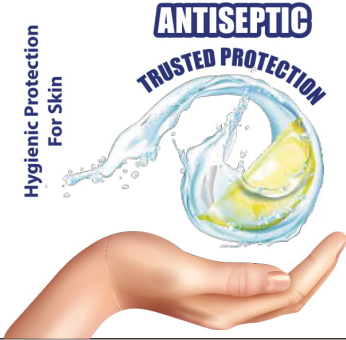


**BACTERIA**  
Pseudomonas Aeruginosa ✓ Coli

**BACTERIA**

✓ Pseudomonas Aeruginosa ✓ Coli  
✓ Staphylococcus Aureus ✓ Enterococcus Hirae

100 mm



ANTI-BACTERIAL  
Wet wipes



410 mm

90 mm

**BACTERIA**  
✓ Pseudomonas Aeruginosa ✓ Coli  
✓ Staphylococcus Aureus ✓ Enterococcus Hirae



50 mm

Made in Turkey

**Name and address of the manufacturer**  
 SCK ZETA KIMYA TEMIZLIK VE KOZMETIK URUNLERI SAN. TIC. LTD. STI.  
 BEYSAN SANAYI SITESI DEREBOYU CAD. NO:28 HARAMIDERE-BEYLÜKÖZÜ/İSTANBUL

**Name and address of the license holder:**  
 SCK ZETA DIŞ TIC.PAZ. LTD.ŞTİ. Mecidiyeköy Mah. Büyükdere Cad. Kuşu İş Merkezi  
 No: 81 K: Kağı No: 4 Şişli İstanbul (Mülga İbare: RG-21/12/2011-28149)

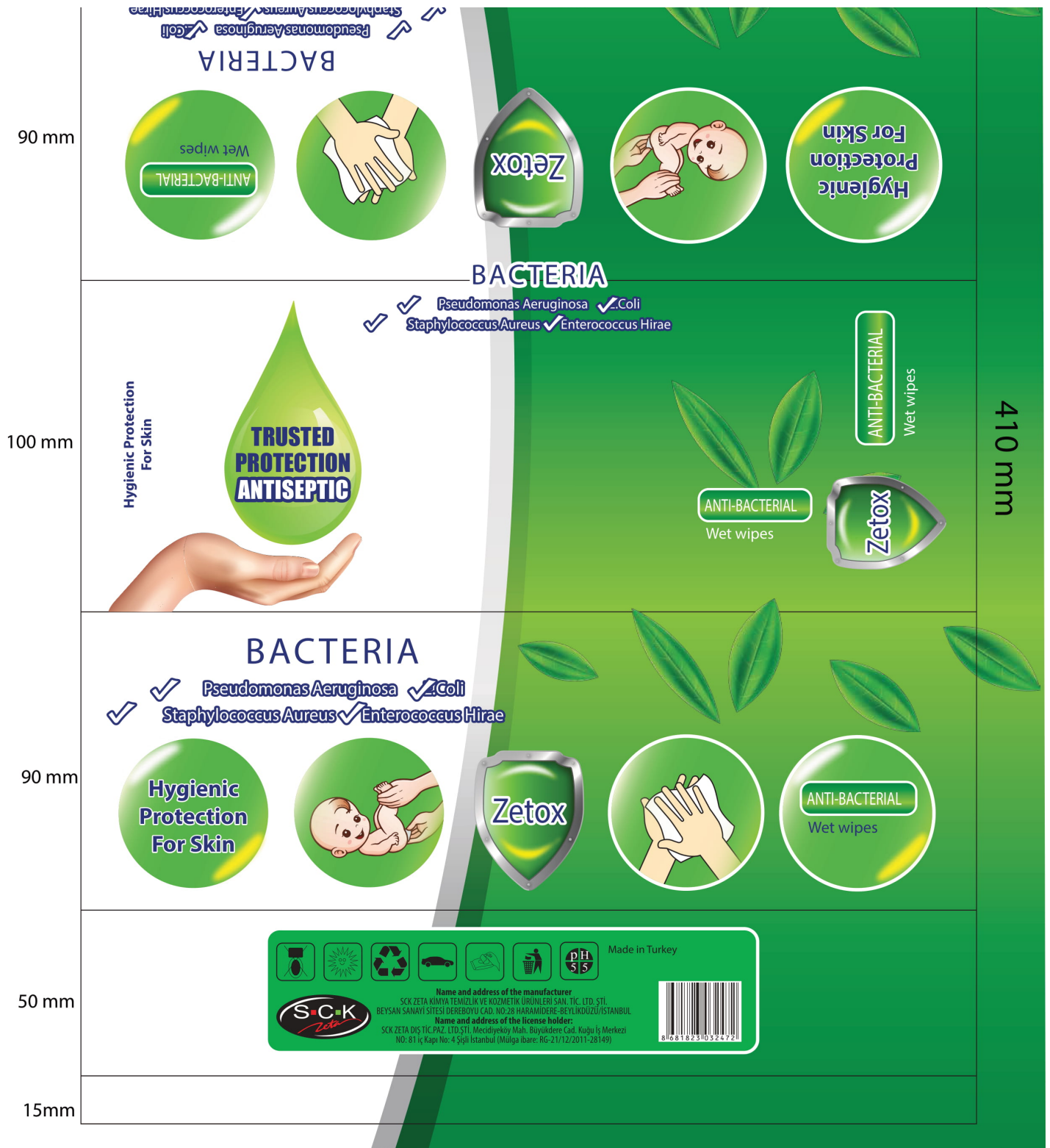
15mm

270 mm

15mm

50 mm

<b>Only facts</b>	<b>Purpose</b>
<b>Active ingredient</b>	Benzalkonium Chloride (0,2 % w/v) ..... Antiseptic
<b>Use</b>	It is a disinfectant product that provides fast cleaning for your skin with its ready-to-use structure. You can easily use it at home, outside in air and during travel. After using, please wash your hands and avoid spreading.
<b>Warnings</b>	For external use only. Please always carefully read the label and the instructions.
<b>Do not use</b>	On open skin wounds.
<b>Shelf life</b>	36 months.
<b>When using this product</b>	Keep away from children, food and animal feeds. Do not eat, drink, or swallow. Follow use instructions to prevent risks on human and environmental health. If contact the skin, this product is produced to contact the skin. Wash the excess with water. In case of redness, swelling, itching or burning rashes get medical help. In case of eye contact, wash the eyes with the clean water at least 15 minutes with the eyes open.
<b>Keep out of reach of children</b>	Flammable, for medical help in contact of skin. Contact your doctor if necessary.
<b>Precautions</b>	Use wipes as much as needed, usually wipe the hand, between the fingers, all internal and external surfaces, and under the nails. Do not reuse after use. Separate children under 3 years of age when using this product to avoid swallowing.
<b>Other informations</b>	Store below 30°C.
<b>Active ingredients</b>	Benzalkonium Chloride, Phenol, Benzoin Acid, Propylparaben, EDTA, Citric Acid, Glycolic Acid, Phosphoric Acid, Citric Acid, Glycerin, Ethylhexylglycerin, Caprylyl Glycol, Parfum, Tetrasodium Edta, Citric Acid.



## ZETOX ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:86818-004
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.2 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>PEG-7 GLYCERYL COCOATE</b> (UNII: VNX7251543)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>MELALEUCA ALTERNIFOLIA LEAF</b> (UNII: G43C57162K)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>ETIDRONATE TETRASODIUM</b> (UNII: CZZ9T1T1X4)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:86818-004-02	120 in 1 PACKAGE	03/30/2020	
1	NDC:86818-004-01	0.74 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:86818-004-04	100 in 1 PACKAGE	03/30/2020	
2	NDC:86818-004-03	0.74 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:86818-004-06	80 in 1 PACKAGE	03/30/2020	
3	NDC:86818-004-05	0.74 g in 1 PATCH; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/30/2020	

**Labeler** - SCK ZETA DIS TICARET (356290986)**Registrant** - SCK ZETA DIS TICARET (356290986)

## Establishment

Name	Address	ID/FEI	Business Operations
SCK ZETA DIS TICARET		356290986	manufacture(86818-004)

Revised: 1/2022

SCK ZETA DIS TICARET