

## **DEEP FRESH ANTIBACTERIAL WET WIPES- benzalkonium chloride cloth AKSAN KOZMETIK 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.*

### **DEEP FRESH ANTIBACTERIAL WET WIPES**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based 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 (0.23%, weight/weight (w/w))
- b. Dehydroacetic Acid
- c. Benzoic Acid
- d. Lauryl Glucoside
- e. Glycerin
- f. Propylene Glycol
- g. Etidronate Tetrasodium
- h. Octadecanoic Acid, (Octadecylimino)Di-2,1-EthanediyI Ester
- i. Fatty-Acid Amide Hydrolase 1
- j. Phenoxyethanol
- k. Dicaprylyl Carbonate
- l. Glyceryl Oleate
- m. Polysorbate 20
- n. Sterile distilled water or boiled cold water.

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 0.23% w/w. Purpose: Antibacterial-Antifungal

### **Purpose**

Antibacterial / Antifungal Wet Wipes

### **Use**

Antibacterial Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

## **Warnings**

Keep away from food and animal feeds. For external use only.

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

When Using this product do not inhale the vapour or grains of the product if occurs. Do not eat or drink or smoke while using the product. Follow all the instructions to avoid risks on human and environmental health. In case of inhaling: Give fresh air or oxygen. If you feel unwell, consult a doctor. In case of skin contact: This product is produced to contact with the skin. Seek a doctor if redness, swelling, itching, or burning occurs on skin. In case of contact with eyes: If you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean water. In case of swallowing: Rinse mouth. Do not vomit. If unconscious, never give anything by mouth. If it is vomiting, do not lay it on its back and lay it on its side. Call your local Toxication Center and get medical help.

Seek a doctor if redness, swelling, itching, or burning occurs on skin.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

### **DIRECTIONS**

Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required.

## **Other information**

Store the product dry, cool, clean place and keep away from direct sunlight. Keep away from children and pets.

## **Inactive ingredients**

Dehydroacetic Acid, Benzoic Acid, Lauryl Glucoside, Glycerin, Propylene Glycol, Etidronate Tetrasodium, Octadecanoic Acid, (Octadecylimino)Di-2,1-Ethanediy Ester, Fatty-Acid Amide Hydrolase 1, Phenoxyethanol, Dicaprylyl Carbonate, Glyceryl Oleate, Polysorbate 20, Sterile distilled water

## **Package Label - Principal Display Panel**

100 pcs NDC: 86815-003-01

385 mm

285 mm

15 mm 50 mm 77.5 mm 100 mm 77.5 mm 50 mm 15 mm

15 mm

50 mm

77.5 mm

100 mm

77.5 mm

50 mm

15 mm

285 mm

285 mm

15 pcs NDC: 86815-003-02



260x155 mm

**DEEPPRESH  
ANTIBACTERIAL WET WIPES**  
NDC Code: xxxxxx

**Drug Facts**

**Active Ingredient**      **Purpose**  
Benzalkonium Chloride 0.23%(w/w).....Antibacterial / Antifungal

**USE:** Antibacterial Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**  
Keep out of reach of children. For external use only.

**DO NOT USE**  
: in children less than 2 months of age  
: on open skin wounds

**WHEN USING**  
Do not eat or drink while using the product. Follow all the instructions to avoid risks on human and environmental health. In case of contact with eyes, if you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean water. If swallowed, get medical help or contact a Poison Control Center right away.


**STOP USE**  
Seek a doctor if redness, swelling, itching, or burning occurs on skin.

**DIRECTIONS**  
Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required. Supervise children under 6 years of age when using this product to avoid swallowing.

**OTHER INFORMATION**  
Store the product dry, cool, clean place and keep away from direct sunlight.

**INACTIVE INGREDIENTS**  
Benzoic Acid, Dihydroacetic Acid, Diacpryl Carbonate, Glycerin, Glyceryl Oleate, Lauryl Glucoside, Olus Oil, Parfum, Phenoxyethanol, Polyglyceryl-2 Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Tetrasodium EDTA, Water

Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Hygienic cleaning at everywhere you need.




# Antibacterial Wet Wipes

pH  
Balanced

Max  
Protection

0%  
Alcohol





**Clean & Fresh  
Effect**

**Kills  
99.9%  
of bacteria\***

Antibakteriyel Islak Mendil

Hygienic cleaning at everywhere you need!






**The product is effective against harmful organisms:**

MICROORGANISMS WHICH THE PRODUCT IS EFFECTIVE	USAGE	DOSE / RANGE OF USE	WHEN NEEDED
Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10536, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404	Antibacterial and Antifungal Wet Wipes: It is used as wiping in the cleaning of bacteria and fungi in the hands. No rinsing is required.	The number of wet wipes used to wipe the hands, arms and desired area is 1.	WHEN NEEDED


Provides practical cleaning without the need of water and soap. It is used for hand cleaning. Open the label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required.

**Commercial name of the product:**  
Antibacterial Wet Wipes  
**Formulation Form:** Solid(Absorbed solution in fabric)  
**Fabric structure:** Nonwoven fabric.  
**Active material name and amount:** Quaternary ammonium compounds, benzyl (C12-C16) alkyl dimethyl, chlorides (Cas No: 68242-85-1) was used at 0,23%.  
**Warnings:** Under normal conditions its shelf life is 2 years. Use the opened product within 3 months. Keep out of reach of children and store in a cool dry place. Avoid direct sunlight and eye contact.  
**Amounts of active ingredient absorbed in wipe are given in the table.**  
Produced under hygienic environment and conditions according to ISO 22716:2007 (GMP) ve ISO 9001:2015 Quality Management System.  
ISO 22716:2007 (GMP) ve ISO 9001:2015 Kalite Yönetim Sistemine uygun olarak hijyenik ortam ve koşullarda üretilmiştir.  
\*Kills 99.9% of Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10536, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404.  
\*Staphylococcus Aureus ATCC 6538, Pseudomonas Aeruginosa ATCC 15442, Enterococcus Hirae ATCC 10541, Escherichia Coli ATCC 10536, Candida Albicans ATCC 10231, Aspergillus Brasiliensis ATCC 16404 in %99.9 unu öldürür.





Üretici Firma : Ruhsat Sahibi  
Adı Ve Adresi / Manufacturer:  
Licence Owner Name And Address:  
Aksan Kosmetik San. ve Tic. A.Ş.  
Dokuz Eylül Mah. Kozak Cad. No:23-23A  
Anadoluyolu / Istanbul / Turkey  
Tel : +90 212 407 04 24  
Fax : +90 212 407 04 26  
www.aksankozmetik.com.tr  
info@aksankozmetik.com.tr



\*Hygienic Products  
Made in Turkey / Üretilmiştir

155 mm x 140mm

**Deep Fresh**

# Antibacterial Wet Wipes

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## Antibakteriyel Islak Mendil

Antibacterial Wet Wipes

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Made in Turkey / Üretilmiştir

**Drug Facts**

**Active Ingredient**      **Purpose**  
Benzalkonium Chloride 0.23%(w/w).....Antibacterial / Antifungal

**USE:** Antibacterial Wet Wipes to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

**Warnings**  
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**OTHER INFORMATION**  
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**INACTIVE INGREDIENTS**  
Benzoic Acid, Dihydroacetic Acid, Diacpryl Carbonate, Glycerin, Glyceryl Oleate, Lauryl Glucoside, Olus Oil, Parfum, Phenoxyethanol, Polyglyceryl-2 Dipolyhydroxystearate, Polysorbate 20, Propylene Glycol, Tetrasodium EDTA, Water

NDC Code:xxxxxxx

305x155mm

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ANTIBACTERIAL WET WIPES**  
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**100  
PCS**

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barcode



**aksan  
kozmetik**

Üretim Firması: Rubat Sabunlar Adı ve Adresi / Manufacturer: Üretim Firması Adı ve Adresi: Akşan Kozmetik San. ve Tic. A.Ş. Çekirgeç Sok. No: 12/205. Armutlu / Beşiktaş / İstanbul / Türkiye Tel: +90 212 407 34 25 Fax: +90 212 407 34 26 www.aksankozmetik.com.tr info@aksankozmetik.com.tr



**100  
PCS/AD**

370mm x 155 mm

**DEEPFRESH ANTIBACTERIAL WET WIPES**  
NDC Code:xxxxxxx

**Drug Facts**

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**Antibakteriyel Islak Mendil**

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**160  
PCS**

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barcode



**aksan  
kozmetik**

Üretim Firması: Rubat Sabunlar Adı ve Adresi / Manufacturer: Üretim Firması Adı ve Adresi: Akşan Kozmetik San. ve Tic. A.Ş. Çekirgeç Sok. No: 12/205. Armutlu / Beşiktaş / İstanbul / Türkiye Tel: +90 212 407 34 25 Fax: +90 212 407 34 26 www.aksankozmetik.com.tr info@aksankozmetik.com.tr



**160  
PCS/AD**

# DEEP FRESH ANTIBACTERIAL WET WIPES

benzalkonium chloride cloth

## Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:86815-003

**Route of Administration**

TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.23 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>OCTADECANOIC ACID, (OCTADECYLIMINO)DI-2,1-ETHANEDIYL ESTER</b> (UNII: X0S2P50TYC)	
<b>FATTY-ACID AMIDE HYDROLASE 1</b> (UNII: E747F394ZQ)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>ETIDRONATE TETRASODIUM</b> (UNII: CZZ9T1T1X4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86815-003-01	100 g in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
2	NDC:86815-003-02	15 g in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
3	NDC:86815-003-04	80 in 1 CANISTER	03/30/2020	
3	NDC:86815-003-03	0.238464 g in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:86815-003-06	100 in 1 CANISTER	03/30/2020	
4	NDC:86815-003-05	0.29808 g in 1 PATCH; Type 0: Not a Combination Product		
5	NDC:86815-003-08	160 in 1 CANISTER	03/30/2020	
5	NDC:86815-003-07	0.4769 g in 1 PATCH; Type 0: Not a Combination Product		
6	NDC:86815-003-10	500 in 1 CANISTER	03/30/2020	
6	NDC:86815-003-09	1.4904 g in 1 PATCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part333A	03/30/2020	
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**Labeler** - AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (365577706)

**Registrant** - AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (365577706)

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		365577706	manufacture(86815-003)

Revised: 4/2022

AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI