

**FRESHMAKER ANTISEPTIC WET WIPES- benzalkonium chloride cloth**  
**FULYA KOZMETIK ISLAK MENDIL IMALAT VE PAZARLAMA LIMITED 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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**Freshmaker ANTISEPTIC HAND WIPES**

**Drug Facts**

**Active ingredient**

Benzalkonium chloride 0.13%

**Purpose**

Antiseptic

**Uses**

- hand wipes to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

**Warnings**

**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 get into eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if**

- irritation and redness develop
- 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**

- open resealable label. Pull out wipes. Close resealable label to prevent drying out
- wipe hands thoroughly with product and allow to dry
- dispose the wipe after use
- supervise children under 6 years of age when using this product to avoid swallowing
- do not flush

**Other information**

- store between 15-30°C(59-86°F)
- avoid freezing and excessive heat above 40°C(104°F)

### ***Inactive Ingredients***

benzoic acid, citric acid, cocamidopropyl betaine, dehydroacetic acid, fragrance, glycerin, PEG-7 glyceryl cocoate, phenoxyethanol, polysorbate 20, propylene glycol, tetrasodium EDTA, water

ANTISEPTIC AGENT

BENZALKONIUM CHLORIDE

**Manufactured by :** Fulya Kozmetik Islak Mendil Iml. ve Paz.Ltd.Sti.

Kirac Osmangazi Kucuk Ayazma Street No:17

34522, Esenyurt/ISTANBUL/TURKEY

P: +90 212 689 28 28 Fax: +90 212 689 82 28

**Made in TURKEY**

☐**Web:** <http://www.fulyakozmetik.com>

**e-mail:** [fulya@fulyakozmetik.com.tr](mailto:fulya@fulyakozmetik.com.tr)

**Lot No:**

**Expiry:**

**You may also report any serious side effects to**

☐PO BOX 328, Wood Ridge, NJ 07075-328

<b>Antibacterial Wet Wipes</b>	
<b>Net Quantity</b>	<b>15 pcs</b>
<b>Size of 1 Dry Tissue</b>	<b>18x13 cm</b>
<b>Weight of 1 Dry Tissue</b>	<b>0.82gr/pc ± % 10</b>
<b>Quantity of Solution Absorbed in the Tissue</b>	<b>2.87gr/pc ± % 10</b>
<b>Weight of Solution-Absorbed Cloth (Solution+Cloth)</b>	<b>3.69gr/pc ± % 10</b>
<b>Solution % / Cloth %</b>	<b>% 77.81 / 22 19</b>
<b>***Quantity of Active Substance Absorbed in the Tissue</b>	<b>0,0037 gr/pc ± % 10</b>

<b>Antibacterial Wet Wipes</b>	
<b>Net Quantity</b>	<b>72pcs</b>
<b>Size of 1 Dry Tissue</b>	<b>18x15 cm</b>
<b>Weight of 1 Dry Tissue</b>	<b>1,03 gr/pc ± % 10</b>
<b>Quantity of Solution Absorbed in the Tissue</b>	<b>3,6 gr/pc ± % 10</b>
<b>Weight of Solution-Absorbed Cloth (Solution+Cloth)</b>	<b>4,64 gr/pc ± % 10</b>
<b>Solution % / Cloth %</b>	<b>% 77.81 / 22 19</b>
<b>***Quantity of Active Substance Absorbed in the Tissue</b>	<b>0,0047 gr/pc ± % 10</b>

# Antibacterial Wet Wipes

Net Quantity	120 pcs
Size of 1 Dry Tissue	18x15 cm
Weight of 1 Dry Tissue	1,03 gr/pc ± % 10
Quantity of Solution Absorbed in the Tissue	3,6 gr/pc ± % 10
Weight of Solution-Absorbed Cloth (Solution+Cloth)	4,64 gr/pc ± % 10
Solution % / Cloth %	% 77.81 / 22 19
*** Quantity of Active Substance Absorbed in the Tissue	0,0047gr/pc ± % 10

## Packaging

The packaging design features two color schemes: orange/lemon and green/lime. Each pack is labeled 'ANTISEPTIC WET WIPES' and 'ANTISEPTIC AGENT BENZALKONIUM CHLORIDE'. The 'Freshmaker' brand name is prominently displayed. The packaging includes detailed 'Drug Facts' information and a barcode.

### Drug Facts

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Kirac Osmangazi Kucuk Ayazma Street No:17,  
Esenyurt, Istanbul, TURKEY-34522

**Made in TURKEY**

**You may also report any serious side effects to**  
PO Box 328, Wood Ridge, NJ 07075-328

**Use of Antibacterial Wet Wipes:**

1 wet wipe is used in order to clean the bacteria in the hand and palm. Tissues taken from the package properly are used and the required cleaning is ensured.

The wastes are junked at the end of the application.

**USER GROUP**

(General Public)

**READ THE LABEL BEFORE USE**

Antibacterial Wet Wipes

Net Quantity of 120 pcs: 500,1 gr 17,64 oz, ±10%

Shelf life is 2 years under normal conditions.

Use of the opened product within 6 months.

Formulation: Solid (Solution-absorbed Wipe)

Structure of the Cloth: Non-woven (Non-woven cloth)

Name and Quantity of the Active Substance:

Benzalkonium Chloride

of 50% in the concentration

of 0,26% (w/w) Net Rate: 0,13%

\*\*\* Quantity of Solution Absorbed in the Tissue is given in the table.

CAS No: 68424-95-1

NOT TESTED ON ANIMALS

**KEEP AWAY FROM FOOD AND ANIMAL FEEDS. DO NOT INHALE THE VAPOR OR GRANULES. DO NOT EAT, DRINK AND SMOKE DURING THE APPLICATION AND PREPARATION. FOLLOW THE INSTRUCTION FOR USE IN ORDER TO PREVENT THE RISKS ON THE HUMAN AND ENVIRONMENTAL HEALTH.**

**Disposal of the Empty Pack:** Do not throw into the environment. Use a rubbish bin. Dispose them properly.

**PRODUCT TYPE (1)**

Biocidal Product on the human hygiene

Intoxication Symptoms: None

Benzalkonium Chloride

Oral (LD50) Acute: 344 mg/kg

Dermal LD50 2848 mg/kg

Citric Acid (5949-29-1)

LD50 oral 5400 mg/kg

LD50 oral 5040 mg/kg

LD50 through skin > 2000 mg/kg

Tetrasodium ethylene diamine tetrasetate (64-02-8)

LD50 oral 1913 mg/kg

**First Aid Measures and Required Information**

General: In case of exposure or interaction, receive medical aid / care.

Aspiration: Take the person to the fresh air and ensure him to breath easily

**Contact with Skin:** Wash the skin with plenty of water. Take off your dirty clothes. In case of irritation on the skin, receive medical aid / care.

**Contact with Eyes:** Rinse with water carefully for a few minutes. If contact lenses are available and if they are easy to remove, then remove them. Rinse continuously. If the eye irritation is permanent, receive medical aid / care.

**Swallowing:** If you do not feel well, call National Poison Counseling Center (UZEM) via the phone number 114 or the doctor / physician.

**The product has no special antidote.**

**Treatment:** The treatment is made depending on the symptoms.

**IN CASE OF INTOXICATION, CALL NATIONAL POISON COUNSELING CENTER (UZEM) VIA THE PHONE NUMBER 114**

**Matters to be Considered While Using and Storing the Product**

**Storage:** Ensure the workplace to be well-ventilated. Do not handle without reading and understanding all the precaution statements. Do not eat, drink and smoke while using the product.

**It may be toxic against the fish and aquatic organisms, Toxic for bees.**

**HARMFULNESS PHRASE AND EXPLANATION**

H 412 – Long term permanent and harmful effect in the aquatic environment

**PRECAUTION PHRASE AND EXPLANATION**

P273 – Avoid giving to the environment

P501 – Dispose the content / package in the harmful or special waste area according to local/regional/national/international regulation.

**Drug Facts**  
**Active Ingredient**  
 Benzalkonium chloride (0.15%)  
**Purpose**  
 Antiseptic

**Uses**  
 • Cleans skin, removes dirt/dust from the skin  
 • recommended for repeated use  
 • for use when soap and water are not available

**Warnings**  
**For external use only.**  
 • Do not use if you are allergic to any of the ingredients listed above.  
 • Do not use on open skin wounds  
 • Do not use in children less than 2 months of age  
 • Do not use in the eyes

• Do not use if you have had an allergic reaction to benzalkonium chloride, or if you have had an allergic reaction to any other antiseptic.  
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**Directions**  
 • Apply liberally to the skin to be treated.  
 • Rub thoroughly for 15-30 seconds.  
 • Rinse thoroughly with water.  
 • Do not use if you have had an allergic reaction to benzalkonium chloride, or if you have had an allergic reaction to any other antiseptic.

**Other Information**  
 • Store between 50°F (10°C) and 80°F (27°C).  
 • Do not use if you have had an allergic reaction to benzalkonium chloride, or if you have had an allergic reaction to any other antiseptic.

**Inactive Ingredients**  
 benzalkonium chloride, citric acid, fragrance, hydroxyethylcellulose, polyethylene glycol, sodium hydroxide, water, and other antiseptics.

**Manufactured by**  
 FUYA  
 Konya, Turkey  
 Made in TURKEY

**Caution**  
 You may also report any adverse effects to the FDA.  
 1-800-FDA-1088

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NDC 178850-100-72

**ANTISEPTIC WET WIPES**



**ANTISEPTIC AGENT**  
 BENZALKONIUM CHLORIDE

5.9 X 7.1 Inch (15X18cm)  
**72 WIPES**

NDC 178850-100-72

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**Freshmaker**



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 FUYA  
 Konya, Turkey  
 Made in TURKEY

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Antiseptic Wet Wipes	
Net Content	72 Wipes
Weight	150g
Volume	150ml
Dimensions	150mm x 180mm
Material	Non-woven fabric
Color	White
Expiration Date	12 Months



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Benzalkonium Chloride 0.13% Antiseptic

**Uses**

- hand wipes to decrease bacteria on the skin
- disinfectant for surfaces
- for use when soap and water are not available

**Warnings**

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**Directions**

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- wipe hands thoroughly with product and allow to dry
- use the wipe after use
- supervise children under 6 years of age when using this product to avoid swallowing

**Other information**

- avoid freezing and excessive heat above 40°C (104°F)

**Inactive ingredients** benzoic acid, citric acid, cocamidopropyl betaine, glycerol, polyethylene glycol, polyethylene glycol, polyethylene glycol, polyethylene glycol, polyethylene glycol, propylene glycol, tetrasodium EDTA, water

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Kıracı Çarşısı, Kuzey Ayazma, Street No:17, Etiler, Beşiktaş, İstanbul, TÜRKİYE 34392  
Made in TURKEY

You may also report any serious side effects to FDA by calling Wood Hogg, NJ 07075-2339

NDC: 78850-120-15

**ANTISEPTIC WET WIPES** 

**Freshmaker®**

ANTISEPTIC AGENT  
BENZALKONIUM CHLORIDE

5.12x7.1 inch (13x18cm)  
**15 WIPES**

5.12x7.08 inch (13x18cm)  
**15 WIPES**

**Freshmaker®**

ANTISEPTIC AGENT  
BENZALKONIUM CHLORIDE

ANTISEPTIC WET WIPES 

**FULYA**

ANTISEPTIC WET WIPES

ANTISEPTIC AGENT  
BENZALKONIUM CHLORIDE

CODE: PM81  
Lot No:  
Expiry:

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
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CODE: PM81  
Lot No:  
Expiry:

# FRESHMAKER ANTISEPTIC WET WIPES

benzalkonium chloride cloth

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78850-120
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEG-7 GLYCERYL COCOATE</b> (UNII: VNX7251543)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78850-120-15	15 in 1 PACKET	07/01/2020	
1		2.87 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:78850-120-72	72 in 1 PACKET	07/01/2020	
2		3.6 g in 1 PACKAGE; Type 0: Not a Combination Product		
3	NDC:78850-120-00	120 in 1 PACKET	07/01/2020	
3		3.6 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	07/01/2020	

**Labeler** - FULYA KOZMETIK ISLAK MENDIL IMALAT VE PAZARLAMA LIMITED SIRKETI (356117981)

### Establishment

Name	Address	ID/FEI	Business Operations
FULYA KOZMETIK ISLAK MENDIL IMALAT VE PAZARLAMA LIMITED SIRKETI		356117981	manufacture(78850-120)