

ABUTOL ANTISEPTIC WET WIPES CITRUS GARDEN- benzalkonium chloride cloth
FULYA KOZMETİK ISLAK MENDİL İMALAT VE PAZARLAMA LIMITED SİRKETİ

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.

ABUTOL CITRUS GARDEN ANTISEPTIC WET 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, PARIS
ANTISEPTIC AGENT

You may also report any serious side effects to

PO BOX 328, Wood Ridge, NJ 07075-328

Distributed By: American Brands and More LLC, Wood Ridge, NJ 07075

Antibacterial Wet Wipes	
Net Quantity	20 pcs
Size of 1 Dry Tissue	18x13 cm
Weight of 1 Dry Tissue	0.82gr/pc ± % 10
Quantity of Solution Absorbed in the Tissue	2.87gr/pc ± % 10
Weight of Solution-Absorbed Cloth (Solution+Cloth)	3.69gr/pc ± % 10
Solution % / Cloth %	% 77.81 / 22.19
***Quantity of Active Substance Absorbed in the Tissue	0,0037 gr/pc ± % 10

Packaging

Drug Facts	Purpose Benzalkonium chloride 0.13%.....Antiseptic
Active Ingredient	
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

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


NDC: 78850-103-01


ANTISEPTIC WET WIPES 

Abutel

ANTISEPTIC AGENT
BENZALKONIUM CHLORIDE








ANTISEPTIC **WET WIPES**

5.1X7.1 Inch(13X18cm)
20 WIPES

Citrus Garden

5.1X7.1 Inch(13X18cm)
20 WIPES



ANTISEPTIC **WET WIPES**

ANTISEPTIC AGENT
BENZALKONIUM CHLORIDE

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 assured.
The wastes are junked at the end of the application.
USE GROUP
(General Public)
READ THE LABEL BEFORE USE
Antibacterial Wet Wipes
Net Quantity of 20 Wipes: Size 1.94 oz. ± 10%
Shelf life is 2 years under normal conditions.
Use of the opened product within 6 months.
Precautions: Solid (Soluble-absorbed Wipe)
Structure of the Solid: Non-woven (Non-woven cloth)
Name and Quantity of the Active Substance:
Benzalkonium Chloride
of 0.13% in the concentration
of 0.26 % (w/v) Net Wt: 0.13%
*** Quantity of Solvent Absorbed in the Tissue is given in the table.
CAS No: 80454-88-1
NOT TESTED ON ANIMALS

KEEP AWAY FROM FOOD AND ANIMAL FEEDS.
DO NOT SWALLOW THE WIPES 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 Packs: Do not throw into the environment. (Use a rubbish bin, dispose them properly).
PRECAUTION TYPE (I)
Steadily Present on the human hygiene
Indication: Symptomatic Use
Benzalkonium Chloride
0.13% (0.26% Active) 144 mg/kg
Benzal 1440 2880 mg/kg
Chloride Acid (9448-29-1)
1440 and 5400 mg/kg
1440 and 5400 mg/kg
1440 through 5400 mg/kg
Tetraedimethyl ethylene diamine hydrochloride (64-62-4)
1440 and 1912 mg/kg
First Aid Measures and Required Information
General: In case of exposure or intoxication, 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: Flush 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 eyes continue to pain, receive medical aid / care.
Swallowing: If you do not feel well, call National Poison Consulting Center (02396) via the phone number 114 or the doctor / physicians.
The product has no special cautions.
Treatment: The treatment is made depending on the symptoms.
In case of intoxication, call NATIONAL POISON CONSULTING CENTER (02396) VIA THE PHONE NUMBER 114.
Batteries to be Conserved While Using and Storing the Product
Storage: Ensure the container 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.
HAZARDOUS PHRASE AND EXPLANATION
H 412 - Long term persistent and harmful effect in the aquatic environment
PRECAUTION PHRASE AND EXPLANATION
P223 - Avoid giving to the environment
P301 - Dispose the content / package in the harmful or special waste area according to local/regional/national/international regulations.

Antibacterial Wet Wipes

Net Quantity	20 pcs
Size of 1 Dry Tissue	18x13 cm
Weight of 1 Dry Tissue	0.62g/pc ± % 10
Quantity of Solvent Absorbed in the Tissue	2.87g/pc ± % 10
Weight of Solvent-Absorbed Cloth (Glycerin+Glycol)	3.49g/pc ± % 10
Solvent % / Cloth %	% 77.81 / 22.19
***Quantity of Active Substance Absorbed in the Tissue	0.0037 g/pc ± % 10

Distributed By: American Brands and More LLC, Wood Ridge, NJ 07075



Lot No:

Expiry:

6 87368 33065 1

Drug Fact Table

Drug Facts	
Active ingredient	Purpose
Benzalkonium chloride 0.13%.....	Antiseptic
Uses	
<ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ in children less than 2 months of age ■ on open skin wounds 	
When using this product	<ul style="list-style-type: none"> ■ do not get into eyes. In case of contact, rinse eyes thoroughly

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

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 20 pcs: 55gr 1,94 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: 68424-85-1

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 tetraacetate (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.

ABUTOL ANTISEPTIC WET WIPES CITRUS GARDEN

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78850-103	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6 Y)		BENZALKONIUM CHLORIDE	0.13 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
BENZOIC ACID (UNII: 8SKN0B0MIM)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
DEHYDROACETIC ACID (UNII: 2KAG279R6R)				
GLYCERIN (UNII: PDC6A3C0OX)				
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
EDETATE SODIUM (UNII: MP1J8420LU)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78850-103-01	20 in 1 PACKET	08/28/2020	
1		2.87 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	08/28/2020	

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(78850-103)