

**ABUTOL ANTISEPTIC WET WIPES LEMON AND MINT- 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 Lemon & Mint 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

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

Package 20 Wipes



Drug Facts	
Active ingredient	Purpose
Benzalkonium chloride 0.13%.....	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	

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 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.

ABUTOL ANTISEPTIC WET WIPES LEMON AND MINT

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78850-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	0.13 g

UNII:7N6JUD5X6Y)	CHLORIDE	in 100 g
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Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MM)	
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:78850-101-01	20 in 1 PACKET	09/01/2020	
1		2.87 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:78850-101-02	120 in 1 PACKET	09/01/2020	
2		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	09/01/2020	

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(78850-101)