# 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.

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### **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-Ethanediyl Ester
- i. Fatty-Acid Amide Hydrolase 1
- j. Phenoxyethanol
- k. Dicaprylyl Carbonate
- I. 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 vomiting. 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 rising required.

## Other information

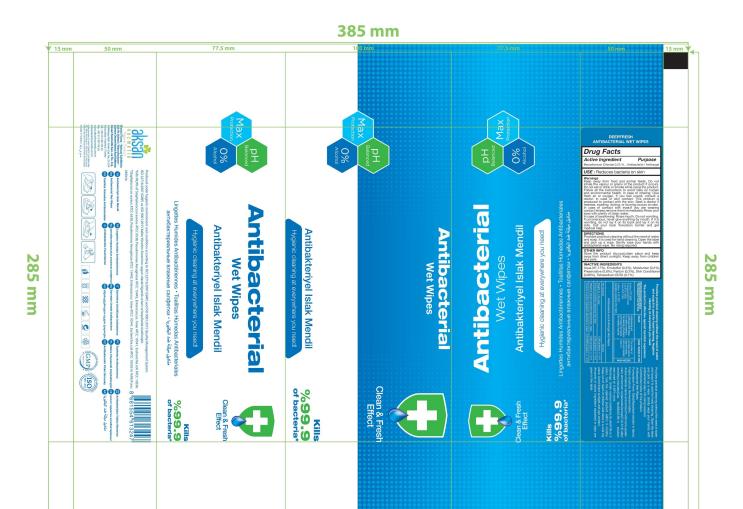
Store the product dry,cool,clean place and keep away from direct sunlight. Keep away from children and pets.

## Inactive ingredients

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

## Package Label - Principal Display Panel

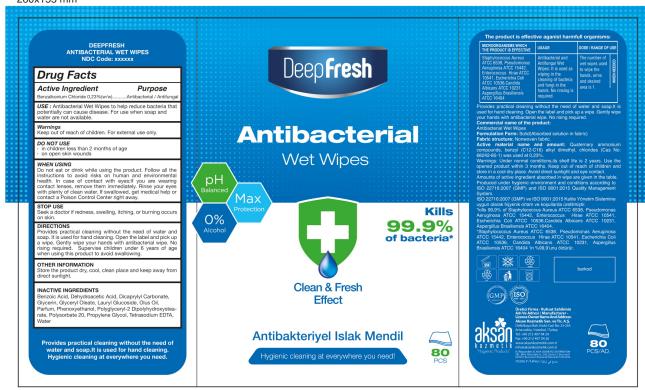
100 pcs NDC: 86815-003-01



15 pcs NDC: 86815-003-02

## 160mm



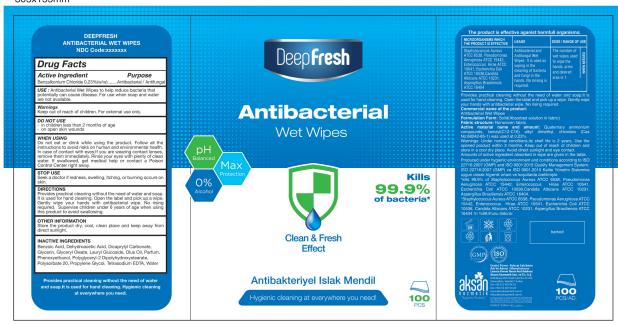


#### 155 mm x 140mm





#### 305x155mm



### 370mm x 155 mm



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

Inactive Ingredients	
Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
OCTADECANOIC ACID, (OCTADECYLIMINO)DI-2,1-ETHANEDIYL ESTER (UNII: X0S2P50TYC)	
FATTY-ACID AMIDE HYDROLASE 1 (UNII: E747F394ZQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	

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

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

OTC monograph not final	part333A	03/30/2020	

## Labeler - AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (365577706)

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

Establishment				
Name	Address	ID/FEI	<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