

**MEDIFRESH HAND SKIN ANTISEPTIC DISINFECTANT WET WIPES- alcohol-
benzalkonium chloride cloth**

KARDESLER UCAN YAGLAR SANAYI 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.

MEDIFRESH HAND&SKIN ANTISEPTIC DISINFECTANT 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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Benzalkonium Chloride (0.1% w/w).
- c. Glycerol (0.2% w/w).
- d. Tocopheryl Acetate (0.05% w/w)
- e. Propylene Glycol (0.2% w/w).
- f. Aloe Barbadensis Extract (0.02% w/w)
- g. Citric acid (0.04% w/w)
- h. 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)

Alcohol 80% w/w

Benzalkonium Chloride 0.1% w/w .

Purpose: Antiseptic

Purpose

Antiseptic, Hand & Skin Sanitizer

Use

Skin should be rubbed vigorously with the wet wipe. No need to rinse after usage. Allow skin to dry without wiping. For adults and children 2 years and over.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

do not use

- as baby wipe

- on open skin wounds
- if you are allergic to any other ingredient.

When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

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

Stop use and ask a doctor if irritation or allergic reaction occurs.

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

Directions

- Open container plastic cover. Tear off aluminum cover. From center of wipe roll, pull up wipe corner; Twist wipe corner from the center plastic cap, thread through the hole. Pull through about one inch. Replace plastic cover. Pull out wipes as needed and snap off at 90 angle. Wipe skin, hands, wrist and elbow ensuring wetting completely. Do not rinse after usage. Keep center cap closed to prevent moisture loss. Discard properly after use.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store in dry and cool place and away from oxidizers.
- May discolor some fabrics, harmful to wood finishes and plastics.

Inactive ingredients

Aqua, Glycerol, Propylene Glycol, Parfum, Tocopheryl Acetate, Citric acid, Aloe Barbadensis Extract

Package Label - Principal Display Panel

80 PCS NDC: 86937-002-02

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol 80.0 % w / w.....</td> <td>Antiseptic</td> </tr> <tr> <td>Benzalkonium Chloride 0.1 % w / w.....</td> <td>Antiseptic</td> </tr> </tbody> </table> <p>Uses To decrease bacteria on the skin that could cause disease</p> <p>Warnings For external use only. Flammable - Keep away from heat or flame Do not use</p> <ul style="list-style-type: none"> • as baby wipe • on open skin wounds • if you are allergic to any of the ingredients <p>When using this product do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation, or allergic reaction occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions Skin should be rubbed vigorously with the wet wipe. No need to rinse after usage. Allow skin to dry without wiping. For adults and children 2 years and over. Open container plastic cover. Tear off aluminum cover. From center of wipe roll, pull up wipe corner; twist wipe corner from the center plastic cap, thread through the hole. Pull through about one inch. Replace plastic cover. Pull out wipes as needed and snap off at 90° angle. Keep center cap closed to prevent moisture loss. Discard properly after use. Supervise children under 6 years of age when using this product to avoid swallowing.</p> <p>Other Information Store in dry and cool place and away from oxidizers. May discolor some fabrics, harmful to wood finishes and plastics.</p> <p>Inactive ingredients Aqua, Glycerin, Propylene Glycol, Parfum, Tocopheryl Acetate, Citric Acid, Aloe Barbadensis Extract</p>	Active Ingredients	Purpose	Ethyl Alcohol 80.0 % w / w.....	Antiseptic	Benzalkonium Chloride 0.1 % w / w.....	Antiseptic	<h2>Hand & Skin Antiseptic Disinfectant Wet Wipes</h2>  <p>80% Alcohol</p> <p>Moisturizer</p> <p>Aloe Vera</p> <p>Vitamin E</p> <p>Decrease Bacteria that could cause disease</p> <p>80.0 % Ethyl Alcohol - 0.1 % Benzalkonium Chloride Non - Sterile Wet Wipe</p> <p>medifresh</p>	 <p>KARDEŞLER ÜÇAR TAĞLAR SANAYİ A.Ş. 1987</p> <p>ISO 9001 Quality Management System ISO 22716 Good Manufacturing Practices</p> <p>80 Pcs</p> <p>Made In Turkey</p> <p>8 69374 617102</p> <p>Danger</p> <p>NDC Code: 86937-002</p>
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/20/2020	

Labeler - KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI (644389322)

Registrant - KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI (644389322)

Establishment

Name	Address	ID/FEI	Business Operations
KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI		644389322	manufacture(86937-002)

Revised: 8/2020

KARDESLER UCAN YAGLAR SANAYI ANONIM SIRKETI