

**MANOLIA DISINFECTANT WET WIPE- benzalkonium chloride cloth  
TELLINI INC.**

*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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**MANOLIA DISINFECTANT WET WIPE**

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 (0.45%, volume/volume (w/v)) in an aqueous solution.
- b. Glycerol (0.8% w/v).
- c. Phenoxyethanol (0.1% w/v).
- d. Cocamidopropyl Betaine (0.4% w/v).
- e. Polysorbate 20 (0.2% w/v).
- f. Peg-7 Glyceryl Cocoate (0.3% w/v).
- g. Citric Acid (0.1% w/v).
- 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)**

Benzalkonium Chloride 0.45% w/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. 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 keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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 rash occurs. These may be signs of a serious condition.

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

**Directions**

- Open package, remove one wet wipes to clean your hands and body. Reseal, keep closed to prevent evaporation.
- Allow to dry without wiping. Discard properly after use.
- Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

- Store at room temperature.
- Do not flush down toilet.

**Inactive ingredients**

Citric acid, Cocoamidopropyl betaine, glycerin, Phenoxyethanol, Polysorbate 20, Peg-7 glyceryl cocoate, purified water USP

**Package Label - Principal Display Panel**

72 pcs NDC: 86812-002-01



8 16812421204443

MANUFACTURER  
ARGÜN ÇOCUK BEZİ VE KOZMETİK ÜRÜNLERİ  
SANAYİ VE TİC. LTD ŞTİ.

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www.agunkozmetik.com.tr



72 pcs.

antibacterial  
cleansing cloths






72 pcs.

antibacterial wet towels



ANTIBACTERIAL  
FORMULA

Effective at eliminating  
**99.9%** of  
many common harmful  
germs and bacteria

0.45% Benzalkonium  
chloride with moisturizers  
(Non-sterile Topical Solution)

**Drug Facts**

| Active Ingredient   | Purpose    |
|---|------------|
| Benzalkonium chloride 0.45 % w/v  | Antiseptic |
| <b>Uses</b>   |            |
| Hand sanitizer to help reduce bacteria that potentially can cause disease.<br>For use when soap and water are not available.  |            |
| <b>Warnings</b>   |            |
| For external use only.  |            |
| Do not use  |            |
| <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>  |            |
| When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.<br>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.<br>Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away. |            |
| <b>Directions</b>   |            |
| Open package; remove one wet wipe to clean your hands and body. Reseal; keep closed to prevent evaporation.<br>Allow to dry without wiping. Discard properly after use.<br>Supervise children under 6 years of age when using this product to avoid swallowing.   |            |
| <b>Other Information</b>  |            |
| Store at room temperature<br>Do not flush down toilet   |            |
| <b>Inactive Ingredients</b>   |            |
| Citric acid, Cocamidopropyl betaine, Glycerin, Phenoxyethanol, Polysorbate 20, Peg-7 glyceryl cocoate, Water  |            |

Do not ayrı yazılacaktır  
Ünlem işareti kaldırılması gerekir  
Ayrıca Active ingredient kelime ile rakam arada boşluk olmalıdır

330.00 mm

## MANOLIA DISINFECTANT WET WIPE

benzalkonium chloride cloth

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:80887-004 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength     | Strength       |
|---|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.3 g in 100 g |

## Inactive Ingredients

| Ingredient Name                               | Strength       |
|---|----------------|
| POLYHEXANIDE HYDROCHLORIDE (UNII: 4XI6112496) | 0.3 g in 100 g |
| GLYCEROL FORMAL (UNII: 3L7GR2604E)            | 0.1 g in 100 g |
| WATER (UNII: 059QF0K00R)                      |                |

## Product Characteristics

|                 |  |                     |  |
|-----------------|--|---------------------|--|
| <b>Color</b>    |  | <b>Score</b>        |  |
| <b>Shape</b>    |  | <b>Size</b>         |  |
| <b>Flavor</b>   |  | <b>Imprint Code</b> |  |
| <b>Contains</b> |  |                     |  |

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80887-004-06 | 70 g in 1 CANISTER; Type 0: Not a Combination Product  | 10/25/2020           |                    |
| 2 | NDC:80887-004-05 | 100 g in 1 CANISTER; Type 0: Not a Combination Product | 10/25/2020           |                    |

KILLS 99.9% OF GERMS



**KILLS 99.9% OF VIRUSES & BACTERIA\***

DISINFECTANT WET WIPES

70 WET WIPES  
14.82 Oz (420g)

**KILLS 99.9% OF VIRUSES & BACTERIA**

DISINFECTANT WET WIPES

**Manolia Disinfectant Wipes** Cleans hands, disinfects many household surfaces. Kills 99.9% of viruses & bacteria, allergens and including pet dander, dust mites and pollen. Able to use on electronics: Smartphones, Tablets & Remote Controls.

**ACTIVE INGREDIENTS:**  
Non-alcohol disinfectant wet wipes: 99% pure water, 0.3% PHMB, 0.3% benzalkonium chloride, 0.1 glycerol with jasmine smell

**HAZARD STATEMENTS:**  
Harmful to aquatic organisms may cause long-term adverse effects in the aquatic environment. Avoid direct eye contact.

**KEEP OUT OF REACH OF CHILDREN:**

**DISPOSAL:**  
Dispose of wipes and packaging in accordance to local legislation

**DIRECTION OF USE:**

**Info tab** independently against: EN1276

6 5922 20586 4

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION:** see back panel for additional manufacturer instructions

**ACTIVE INGREDIENTS:**  
Non-alcohol disinfectant wet wipes: 99% pure water, 0.3% PHMB, 0.3% benzalkonium chloride, 0.1 glycerol with jasmine smell

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Harmful to aquatic organisms may cause long-term adverse effects in the aquatic environment. Avoid direct eye contact.

**KEEP OUT OF REACH OF CHILDREN:**

**DISPOSAL:**  
Dispose of wipes and packaging in accordance to local legislation

**DIRECTION OF USE:**

Importer: Tellini Inc.  
New York - USA +1 800 8715060  
manoliashop.com

Recycling symbols: LID (PP), TUB (HDPE), LABEL (PE)

Made in China

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

|                         |          |            |  |
|-------------------------|----------|------------|--|
| OTC monograph not final | part333A | 10/01/2020 |  |
|-------------------------|----------|------------|--|

**Labeler** - TELLINI INC. (117014846)

**Registrant** - TELLINI INC. (117014846)

| <b>Establishment</b>           |                |               |                            |
|--------------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                    | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| DOBOLV (QUANZHOU) PAPER CO LTD |                | 550022046     | manufacture(80887-004)     |

Revised: 10/2020

TELLINI INC.