

**MANOLIA ANTIBACTERIAL 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 Antibacterial 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.

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**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 1681242120443

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

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72 pcs.

antibacterial  
cleansing cloths






72 pcs.

antibacterial wet towels



antibacterial  
cleansing cloths

FORMULA  
ANTIBACTERIAL

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. 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. 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.	
<b>Directions</b>	
Open package; remove one wet wipe 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.	
<b>Other Information</b>	
Store at room temperature 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 ANTIBACTERIAL WET WIPE

benzalkonium chloride cloth

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80887-007
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	0.05 g in 100 g
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	0.2 g in 100 g
<b>BETAINE</b> (UNII: 3SCV180C9W)	0.1 g in 100 g
<b>GLYCEROL FORMAL</b> (UNII: 3L7GR2604E)	0.5 g in 100 g
<b>WATER</b> (UNII: 059QF0K00R)	98.81 g in 100 g
<b>FRAGRANCE LAVENDER ORC1800979</b> (UNII: 1B40MIN2W5)	0.1 g in 100 g
<b>CETYL PYRIDINIUM CHLORIDE ANHYDROUS</b> (UNII: 6BR7T22E2S)	0.05 g in 100 g
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	0.02 g in 100 g

## 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:80887-007-01	70 g in 1 CANISTER; Type 0: Not a Combination Product	10/20/2020	

**KILLS 99.9% OF GERMS**

**Info tab**  
independently against: EN1276

Made in China  
KEEP OUT OF REACH OF CHILDREN  
**CAUTION:** See back panel for important information.

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

**Drug Facts**

Active ingredients	Purpose
Benzalkonium Chloride 0.10%.....	Antibacterial

**Indications and usage**

- For hand washing to decrease bacteria on the skin. Recommended for repeat use.

**Warnings**

- For external use only.
- Keep out of reach of eyes. If contact occurs, rinse thoroughly with water.
- Do not use if you are allergic to any of the ingredients.
- Discontinue use if irritation or redness develops, and if condition persists for more than 72 hours consult a physician.
- Keep out of reach of children unless under adult supervision.
- If swallowed, get medical help.

**Directions of use**

- Wet hands thoroughly with product and allow to dry without rinse.
- Children under six years of age should be supervised when using this product.

**Other Information**

- Store in a dry place away from fire.

**Inactive Ingredients**

- Water(Aqua), Glycerol, Propanediol, Aloe Vera Extract, Amino acid moisturizer, Hexadecylpyridinium Chloride, Vitamin E, Citric acid, Sodium alkylate, Dodecyl polyglycoside.

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
DOBOLV (QUANZHOU) PAPER CO LTD		550022046	manufacture(80887-007)

Revised: 12/2020

TELLINI INC.