

**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.

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.

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Directions

- 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.

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



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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

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

Uses
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 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.

Directions
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.

Other Information
Store at room temperature
Do not flush down toilet

Inactive Ingredients
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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80887-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CHLORPHENESIN (UNII: I670DAL4SZ)	0.05 g in 100 g
PROPANEDIOL (UNII: 5965N8W85T)	0.2 g in 100 g
CETYLPYRIDINIUM CHLORIDE ANHYDROUS (UNII: 6BR7T22E2S)	0.05 g in 100 g
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.02 g in 100 g
BETAINE (UNII: 3SCV180C9W)	0.1 g in 100 g
GLYCEROL FORMAL (UNII: 3L7GR2604E)	0.5 g in 100 g
WATER (UNII: 059QF0K00R)	98.81 g in 100 g
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.3 g in 100 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80887-006-01	70 g in 1 CANISTER; Type 0: Not a Combination Product	10/20/2020	

KILLS 99.9% OF GERMS

KILLS 99.9% OF VIRUSES & BACTERIA*

DISINFECTANT WET WIPES

70 WET WIPES
14.82 Oz (420g)

MANOLIA beauty care

Lemon BLEACH - FREE

KILLS 99.9% OF VIRUSES & BACTERIA

DISINFECTANT WET WIPES

Info tab
independently against: EN1276

6 95922 20586 4

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

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

Drug Facts

Active ingredients Benzalkonium Chloride 0.10%.....**Purpose** Antiseptic

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 citrate, 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(80887-006)

Revised: 11/2020

TELLINI INC.