# 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.

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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

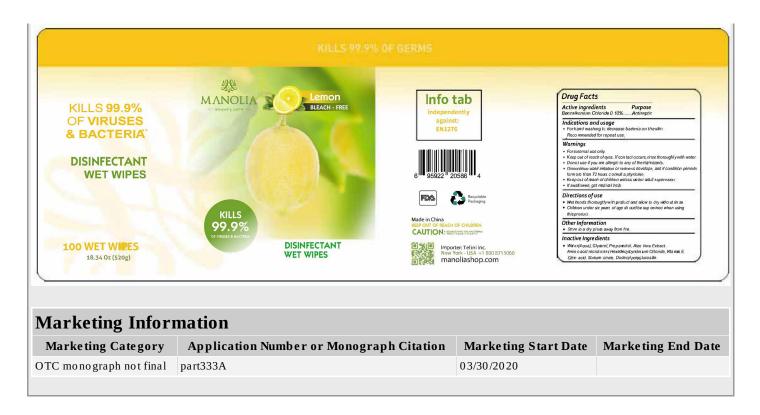
72 pcs NDC: 86812-002-01



## MANOLIA DISINFECTANT WET WIPE

benzalkonium chloride cloth

Product Type	HUMAN OTC DRUG	Item C	Item Code (Source)		NDC:80887-006			
			tem coue (source)					
Route of Administration	TOPICAL							
Active Ingredient/Active I	Moiety							
Ingredient Name				Basis of Strength Stren		Strengtl		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)				BENZALKONIUM 0.1 g CHLORIDE in 100		0.1 g in 100 g		
Inactive Ingredients								
Ingredient Name					Strength			
CHLORPHENESIN (UNII: 1670 DAL4SZ)					0.05 g in 100 g			
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)					0.05g in 100g			
GLYCEROL FORMAL (UNII: 3L7GR2604E)						0.5 g in 100 g		
WATER (UNII: 059QF0KO0R)						98.81 g in 100 g		
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)						0.1 g in 100 g		
PROPANEDIOL (UNII: 5965N8W8		0.2 g in 100 g						
BETAINE (UNII: 3SCV180C9W)						0.1 g in 100 g		
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)					0.05 g in 100 g			
ANHYDROUS TRISODIUM CITR		0.02 g in 100 g						
ANHYDRO US CITRIC ACID (UNI	I: XF417D3PSL)			0.0	2 g in 100 g	5		
Product Characteristics								
Color	Sc	ore						
Shape	Siz							
Flavor		print Code						
Contains		Print Cout						
Packaging								
# Item Code	Package Descrip	tion	Market	ting Start Date	Marketin	ng End Dai		
	<b>.</b> .	STER; Type 0: Not a Combination Product		rketing Start Date Marketin				



## Labeler - TELLINI INC. (117014846)

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

#### **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
DOBOLV (QUANZHOU) PAPER CO LTD		550022046	manufacture(80887-006)

Revised: 11/2020

TELLINI INC.