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 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

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

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: 059QF0KO0R)	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	

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.