WHITEDAY ANTIBACTERIAL WET TOWELS- 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.

WhiteDay Antibacterial Wet Towels

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



WHITEDAY ANTIBACTERIAL WET TOWELS

benzalkonium chloride cloth

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80887-002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
	BENZALKONIUM CHLORIDE	0.45 g in 100 mL		

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	0.8 g in 100 mL			
PHENO XYETHANOL (UNII: HIE492ZZ3T)	0.1 g in 100 mL			
WATER (UNII: 059QF0KO0R)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.2 g in 100 mL			
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	0.3 g in 100 mL			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	0.1 g in 100 mL			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)	0.4 g in 100 mL			

ı	Pá	ackaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:80887-002-01	72 mL in 1 PACKAGE; Type 0: Not a Combination Product	10/25/2020	

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	
TELLINI INC.		1170 148 46	manufacture(80887-002)	

Revised: 10/2020 TELLINI INC.