SOFTIS- benzalkonium chloride cloth Betone, S.A de C.V.

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.

Antibacterial hand sanitizer wipes-BETONE (50 wipes)

Active Ingredient(s)

Benzalkonium chloride 0.13% w/w. 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. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. 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

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, glycerin, DPEG-12 imethicone, Polysobarte 20, Methylisothiazolinone, iodopropinyl

butylcarbameto, PEG-70 Lanolin, fragrance, citric acid and aloe vera.

Package Label - Principal Display Panel

250 g PDP NDC:77824-006-01

124 mm

Softis



ANTIBACTERIAL HAND SANITIZER WIPES

- Free of parabens, formaldehydes and sulphates.
- · Leaves no residue or sticky feeling.
- Practical and efficient cleaning.
- Pleasant frutal fragrance.

50 WET WIPES 6.7" x 6.7"

- 161 mm -

Softis

ANTIBACTERIAL HAND SANITIZER WIPES

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MANUFACTURED BY: Betone S.A de C.V Periférico Poniente #7100, Col. Ciudad. Granja, C.P. 45010, Zapopan, Jal.

MADE IN MEXICO

AM Distributors A Miranda Distributors LLC 270 Catalonia Av. Coral Gables FL 33134



SOFTIS

65

benzalkonium chloride cloth

Drug Facts

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77824-006

Route of Administration	TOPICAL
Route of Administration	TOTICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	0.03 mL in 100 mL	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	0.13 mL in 100 mL	
ABRONIA FRAGRANS FLOWER (UNII: XAV1S68QBA)	0.1 mL in 100 mL	
DIMETHICO NE PEG-7 PANTHENYL PHOSPHATE (12 PANTHENOL) (UNII: 7MA9F33W92)	0.2 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL	
ALOE VERA FLO WER (UNII: 575DY8 C1ER)	0.0004 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	0.13 mL in 100 mL	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.15 mL in 100 mL	
PEG-70 LANOLIN (UNII: 687SBQ855W)	0.1 mL in 100 mL	

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:77824-006-01	250 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	

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

Labeler - Betone, S.A de C.V. (813262755)

Establishment			
Name	Address	ID/FEI	Business Operations
Betone, S.A de C.V.		813262755	manufacture(77824-006), pack(77824-006), label(77824-006)

Revised: 11/2020 Betone, S.A de C.V.