HAND SANITIZER- 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

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)

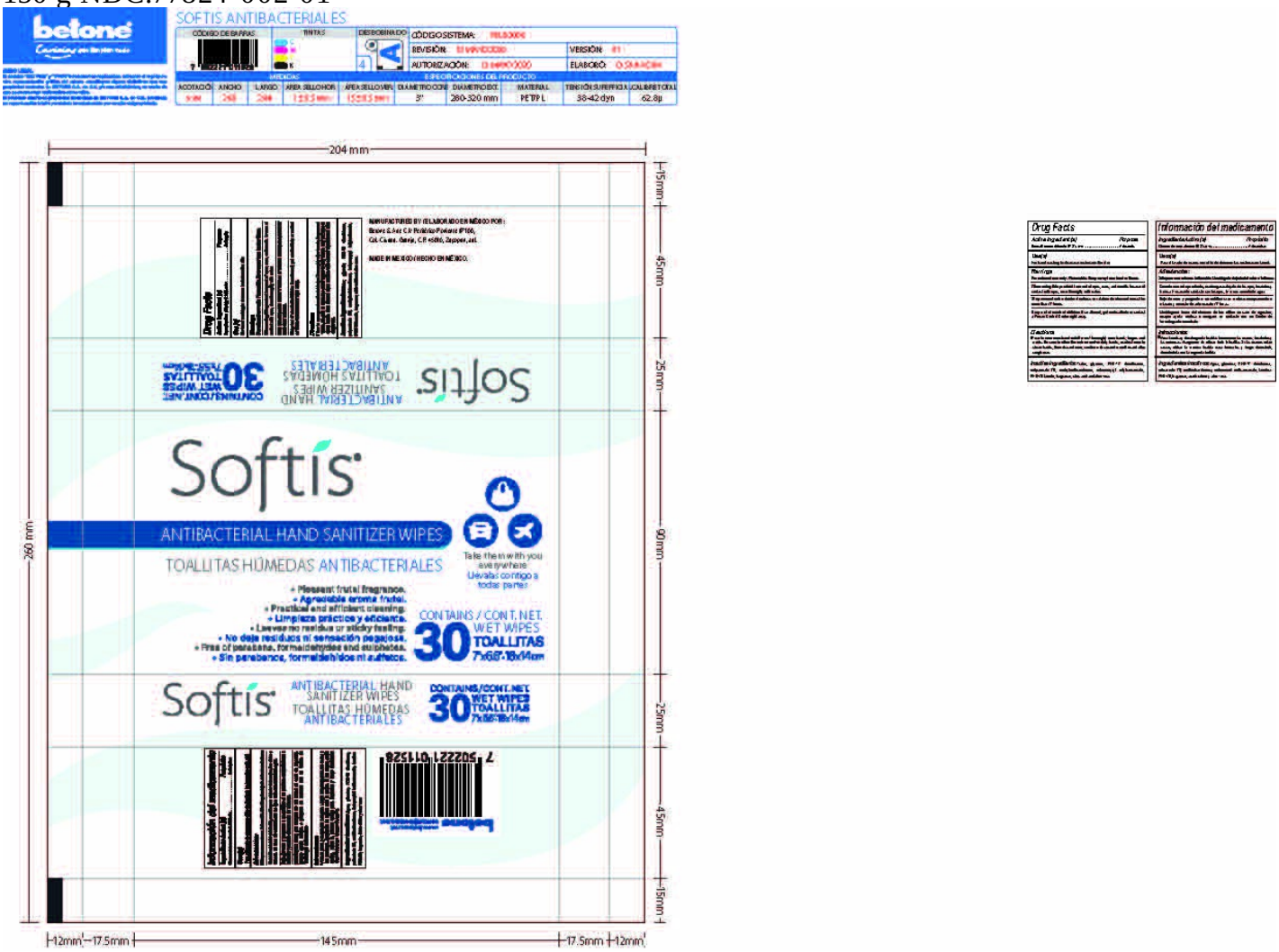
Inactive ingredients

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

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

Package Label - Principal Display Panel

150 g NDC:77824-002-01



HAND SANITIZER

benzalkonium chloride cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77824-002
Route of Administration	TOPICAL		

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 MONOHYDRATE (UNII: 2968PHW8QP)	0.03 mL in 100 mL
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	0.13 mL in 100 mL
ABRONIA FRAGRANS FLOWER (UNII: XAV1S68QBA)	0.1 mL in 100 mL
DIMETHICONE PEG-7 PANTHENYL PHOSPHATE (12 PANTHENOL) (UNII: 7MA9F33W92)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
ALOE VERA FLOWER (UNII: 575DY8C1ER)	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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77824-002-01	150 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(77824-002) , pack(77824-002) , label(77824-002)

Revised: 6/2020 Betone, S.A de C.V.