

## **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.*

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### **Antibacterial hand sanitizer wipes- BET ONE**

#### **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:77824-005-01

|                   |       |             |                        |                        |              |                  |          |                      |                |                  |  |
|-------------------|-------|-------------|------------------------|------------------------|--------------|------------------|----------|----------------------|----------------|------------------|--|
| CÓDIGO DE BARRAS  |       | WIPES       |                        | DESBORNADO             |              | CÓDIGO SISTEMA   |          | REVISIÓN             |                | VERSIÓN          |  |
| 7 825110 122206 2 |       | 30          |                        | A                      |              | 9883000          |          | 11/11/2020           |                | 01               |  |
| AUTORIZACIÓN      |       | ELABORACIÓN |                        | CÓDIGO DE BARRAS       |              | CÓDIGO DE BARRAS |          | CÓDIGO DE BARRAS     |                | CÓDIGO DE BARRAS |  |
| 13 8880 000       |       | O 0000000   |                        | 0 0000000              |              | 0 0000000        |          | 0 0000000            |                | 0 0000000        |  |
| ACCIONES          | ANCHO | LARGO       | ÁREA SECCION           | ÁREA SECCION           | DIAMETRO C/D | DIAMETRO C/D     | MATERIAL | TÉRMINO DE VIDA ÚTIL | CAJAS/PAQUETES |                  |  |
| 5.9%              | 240   | 204         | 1222.3 mm <sup>2</sup> | 1508.3 mm <sup>2</sup> | 3"           | 280-320 mm       | PEPP L   | 30-42 dya            | 62.8j          |                  |  |



| Drug Facts  |                       | Información del medicamento   |   |
|---|-----------------------|---|---|
| Active Ingredient(s)  | Benzalkonium Chloride | Ingredientes Activos  | Benzalkonio cloruro                       |
| Use only as directed.   |                       | Use   | Usar solo de acuerdo a las instrucciones. |
| <b>Warnings</b>   |                       | <b>Advertencias</b>   |   |
| Keep out of reach of children. Do not use if the container is damaged, leaking or the seal is broken. Do not use if the expiration date has passed. Do not use if the product has a strong, unpleasant odor. Do not use if the product has a strong, unpleasant odor. |                       | Keep out of reach of children. Do not use if the container is damaged, leaking or the seal is broken. Do not use if the expiration date has passed. Do not use if the product has a strong, unpleasant odor. Do not use if the product has a strong, unpleasant odor. |   |
| <b>Directions</b>   |                       | <b>Indicaciones</b>   |   |
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## SOFTIS

benzalkonium chloride cloth

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:77824-005 |
| <b>Route of Administration</b> | 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:77824-005-01 | 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(77824-005) , pack(77824-005) , label(77824-005) |

Revised: 7/2020

Betone, S.A de C.V.