

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

belone Caring you the better way		SOFITIS ANTIBACTERIALES	
CÓDIGO DE BARRAS	WIPES	DESBORNADO	CÓDIGO SISTEMA: 98.8.000
REVISIÓN	REVISIÓN	REVISIÓN	REVISIÓN
AUTORIZACIÓN	AUTORIZACIÓN	AUTORIZACIÓN	AUTORIZACIÓN
ELABORADO	ELABORADO	ELABORADO	ELABORADO
ACTIVO	ANCHO	LARGO	AREA SECCION
8.9M	240	234	1223 mm
DIAMETRO DE	DIAMETRO DE	DIAMETRO DE	DIAMETRO DE
3"	280-320 mm	3"	280-320 mm
MATERIAL	TIPO DE SUPERFICIE	TIPO DE SUPERFICIE	TIPO DE SUPERFICIE
PEPP L	30-42 dyp	30-42 dyp	30-42 dyp



Drug Facts	Información del medicamento
Active Ingredient(s) Benzalkonium Chloride 0.13g	Ingredientes Activos Benzalkonium Chloride 0.13g
Warnings Do not use if you are allergic to any of the ingredients listed below. Discontinue use if you experience any of the following symptoms: rash, itching, swelling, dizziness, trouble breathing. For more information on drug interactions, see the Drug Facts label. Keep out of reach of children. See important information about prescription drugs on the inside of this container. This information does not take the place of reading the label on all medicines. Always read and understand all information on the label. Do not use if the seal over the opening is broken. Do not use if the container is damaged. Do not use if the expiration date has passed. Do not use if the product has changed color or has an unusual odor. Do not use if the product has become sticky or clumpy. Do not use if the product has become hard or brittle. Do not use if the product has become lumpy or chunky. Do not use if the product has become watery or milky. Do not use if the product has become cloudy or hazy. Do not use if the product has become discolored or stained. Do not use if the product has become foul smelling. Do not use if the product has become rancid. Do not use if the product has become moldy. Do not use if the product has become infested with insects or other pests. Do not use if the product has become contaminated with any foreign matter. Do not use if the product has become contaminated with any hazardous substances. Do not use if the product has become contaminated with any radioactive materials. Do not use if the product has become contaminated with any toxic substances. Do not use if the product has become contaminated with any carcinogenic substances. Do not use if the product has become contaminated with any mutagenic substances. Do not use if the product has become contaminated with any teratogenic substances. Do not use if the product has become contaminated with any reproductive toxic substances. Do not use if the product has become contaminated with any developmental toxic substances. Do not use if the product has become contaminated with any immunotoxic substances. Do not use if the product has become contaminated with any neurotoxic substances. Do not use if the product has become contaminated with any hepatotoxic substances. Do not use if the product has become contaminated with any nephrotoxic substances. Do not use if the product has become contaminated with any ototoxic substances. Do not use if the product has become contaminated with any teratogenic substances. Do not use if the product has become contaminated with any reproductive toxic substances. Do not use if the product has become contaminated with any developmental toxic substances. Do not use if the product has become contaminated with any immunotoxic substances. Do not use if the product has become contaminated with any neurotoxic substances. Do not use if the product has become contaminated with any hepatotoxic substances. Do not use if the product has become contaminated with any nephrotoxic substances. Do not use if the product has become contaminated with any ototoxic substances.	Advertencias: No usar si usted es alérgico a cualquiera de los ingredientes listados abajo. Dejar de usar si experimenta cualquiera de los siguientes síntomas: erupción, picazón, hinchazón, mareos, dificultad para respirar. Para más información sobre las interacciones de los medicamentos, consulte la etiqueta de los medicamentos. Manténgalo fuera del alcance de los niños. Véase la información importante sobre los medicamentos recetados en el interior de este recipiente. Esta información no reemplaza la lectura de todas las etiquetas de los medicamentos. Siempre lea y entienda toda la información en la etiqueta. No usar si el sello que cubre la abertura está roto. No usar si el envase está dañado. No usar si la fecha de vencimiento ha pasado. No usar si el producto ha cambiado de color o tiene un olor inusual. No usar si el producto se ha vuelto pegajoso o grumoso. No usar si el producto se ha vuelto duro o quebradizo. No usar si el producto se ha vuelto esponjoso o con grumos. No usar si el producto se ha vuelto turbio o opaco. No usar si el producto se ha vuelto manchado o teñido. No usar si el producto se ha vuelto con mal olor. No usar si el producto se ha vuelto rancio. No usar si el producto se ha vuelto mohoso. No usar si el producto se ha vuelto infestado con insectos u otros plagos. No usar si el producto se ha vuelto contaminado con cualquier materia extraña. No usar si el producto se ha vuelto contaminado con cualquier sustancia peligrosa. No usar si el producto se ha vuelto contaminado con cualquier material radiactivo. No usar si el producto se ha vuelto contaminado con cualquier sustancia tóxica. No usar si el producto se ha vuelto contaminado con cualquier sustancia carcinógena. No usar si el producto se ha vuelto contaminado con cualquier sustancia mutagénica. No usar si el producto se ha vuelto contaminado con cualquier sustancia teratogénica. No usar si el producto se ha vuelto contaminado con cualquier sustancia tóxica reproductiva. No usar si el producto se ha vuelto contaminado con cualquier sustancia tóxica del desarrollo. No usar si el producto se ha vuelto contaminado con cualquier sustancia inmunotóxica. No usar si el producto se ha vuelto contaminado con cualquier sustancia neurotóxica. No usar si el producto se ha vuelto contaminado con cualquier sustancia hepatotóxica. No usar si el producto se ha vuelto contaminado con cualquier sustancia nefrotóxica. No usar si el producto se ha vuelto contaminado con cualquier sustancia ototóxica.

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
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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.