

SANITIZING WIPES- benzalkonium chloride cloth

Guangzhou Baihua Co., Ltd

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.

Sanitizing Wipes

Sanitizing Wipes

This is a sanitizing wipe product manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product:

- a. Benzalkonium Chloride (0.13%)
- b. RO pure water
- c. Decyl Glucoside (1%)
- d. Glycerin (2%)
- e. Fragrance (Parfum) (0.03%)
- f. Methylparaben (0.1%)
- g. Phenoxyethanol (1%)
- h. Propylparaben (0.1%)

Active Ingredient(s)

Benzalkonium Chloride 0.13%. Purpose: Antiseptic

Purpose

Antiseptic, Sanitizing Wipes

Use

Sanitizing Wipes to help reduce bacteria on skin. 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, 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

- Wipe hands thoroughly with product.
- Supervise children under 6 years of age when using product.

Other information**Inactive ingredients**

Water (Aqua), Decyl Glucoside, Glycerin, Fragrance (Parfum), Methylparaben, Phenoxyethanol, Propylparaben

Package Label - Principal Display Panel

100 mL NDC: 77665-102-01

		245mm	
		42.5mm	160mm
370mm	10		
	50mm	<div> <div> <div>Drug Facts</div> <div> <div>Active ingredient(s)</div> <div>Benzalkonium Chloride 0.13%</div> <div>Purpose</div> <div>Antiseptic</div> </div> </div> <div> <div>Use(s)</div> <div>Sanitizing Wipes to help reduce bacteria on skin. For use when soap and water are not available.</div> </div> <div> <div>Warnings</div> <div>For external use only.</div> </div> <div> <div>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</div> <div>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</div> <div>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</div> </div> <div> <div>Inactive ingredients</div> <div>Water (Aqua), Deoxy Glucoside, Glycerin, Fragrance (Parfum), Methylparaben, Phenoxyethanol, Propylparaben</div> </div> </div>	
	75mm	<div> <div>Sanitizing Wipes</div> <div>Cleanses and sanitizes in one easy step.</div> <div>Kills 99.9% of germs on hands and skin.</div> <div>NDC 77665-102-01</div> </div>	
	100mm	<div> <div> <div>Kills 99.9% of germs</div> <div>Alcohol Free</div> </div> <div> <div>Sanitizing Wipes</div> <div>Tender Kiss</div> </div> <div> <div>100 Wipes</div> <div>20 cm x 15 cm</div> <div>(7.9 in x 5.9 in)</div> </div> <div> <div>Assured Quality</div> <div>Convenient</div> </div> </div>	
	75mm	<div> <div>Sanitizing Wipes</div> <div>Cleanses and sanitizes in one easy step.</div> <div>Kills 99.9% of germs on hands and skin.</div> <div>NDC 77665-102-01</div> </div>	
	50mm	<div> <div> <div> <div>Directions</div> <div>Wipe hands thoroughly with product.</div> <div>Supervise children under 6 years of age when using product.</div> </div> <div> <div>Other information</div> <div> <div>Tightly seal sticker and close lid between uses to prevent wipes from drying.</div> <div>Dispose of wipe in trash after use. Do not flush.</div> </div> </div> <div> <div>Manufacturer</div> <div> <div>Guangzhou Baihua Co., Ltd</div> <div>Phone: 86-20-87412381</div> <div>Email: baihuas@126.com</div> </div> </div> <div> <div>3 Hongqi Xingye Road, Zhonglutian, Baiyun District, Guangzhou, China</div> <div>6 726915 512500</div> </div> </div> </div>	
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SANITIZING WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77665-102
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 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	1 g in 100 g
METHYLPARABEN (UNII: A2I8C7HI9T)	0.1 g in 100 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.1 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	1 g in 100 g
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	0.03 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77665-102-01	100 g in 1 PACKAGE; Type 0: Not a Combination Product	06/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/18/2020	

Labeler - Guangzhou Baihua Co., Ltd (545015588)

Registrant - Guangzhou Baihua Co., Ltd (545015588)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Baihua Co., Ltd		545015588	manufacture(77665-102)

