# ANTIBACTERIAL WIPES- benzalkonium chloride swab SJ Creations, Inc.

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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### **Drug Facts**

### **Active Ingredient(s)**

Benzalkonium Chloride 0.1% v/v. Purpose: Antiseptic

## Purpose

Antibacterial, Wipe

#### Use

Decrease bacteria on skin. 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**

- Apply to hands
- allow skin to dry without wiping
- Supervise children under 6 years of age when using this product to avoid swallowing.

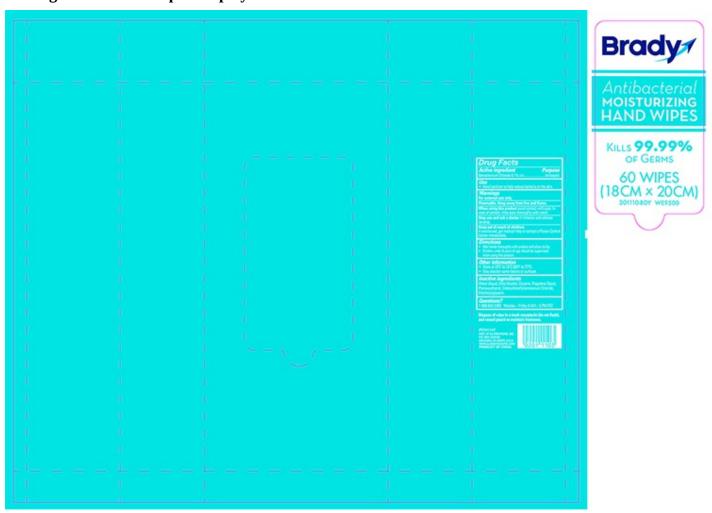
#### Other information

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

#### **Inactive ingredients**

Water, Ethyl Alcohol, Glycerin, Propylene Glycol, Phenoxyethanol, Didecyldimethylammonium Chloride, Exylhexylglycerin.

# Package Label - Principal Display Panel



60ct NDC: 43269-946-60

# **ANTIBACTERIAL WIPES**

benzalkonium chloride swab

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43269-946
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
(	BENZALKONIUM CHLORIDE	0.1 mg in 1 mL	

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	Inactive Ingredients	

Ingredient Name	Strength
DIDECYLDIMO NIUM CHLO RIDE (UNII: JXN40 O9 Y9 B)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:43269-946-60	0.1 mL in 1 POUCH; Type 0: Not a Combination Product	04/30/2020	
Marketing Information				
	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

04/30/2020

# **Labeler -** SJ Creations, Inc. (146379495)

OTC monograph not final part333A

Establishment			
Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528 19 70 42	manufacture(43269-946)

Revised: 4/2020 SJ Creations, Inc.