

## **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, Didecyltrimethylammonium Chloride, Exylhexylglycerin.

### Package Label - Principal Display Panel



60ct NDC: 43269-946-60

## ANTIBACTERIAL WIPES

benzalkonium chloride swab

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43269-946
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>DIDECYLDIMONIUM CHLORIDE</b> (UNII: JXN40O9Y9B)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2020	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528197042	manufacture(43269-946)

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SJ Creations, Inc.