

## **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.

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.

#### **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**




**Drug Facts**

<b>Active ingredient</b> Benzalkonium Chloride 0.1% v/v	<b>Purpose</b> Antiseptic
<b>Use</b> • Hand sanitizer to help reduce bacteria on the skin.	
<b>Warnings</b> <b>For external use only.</b>	
<b>Flammable. Keep away from fire and flame.</b>	
<b>When using this product</b> avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation and redness develop.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions</b> • Wet hands thoroughly with product and allow to dry. • Children under 6 years of age should be supervised when using this product.	
<b>Other information</b> • Store at 20°C to 25°C (68°F to 77°F). • May discolor some fabrics or surfaces.	
<b>Inactive ingredients</b> Water (Aqua), Ethyl Alcohol, Glycerin, Propylene Glycol, Phenoxyethanol, Didecyltrimethylammonium Chloride, Ethylhexylglycerin.	
<b>Questions?</b> 1-888-942-2280 Monday – Friday 9 AM – 5 PM PST	

**Antibacterial  
MOISTURIZING  
HAND WIPES**

KILLS **99.99%**  
OF GERMS

100 WIPES  
(15CM x 20CM)  
WE9503



8 192592 011549

100ct NDC: 43269-959-10

<b>ANTIBACTERIAL WIPES</b>			
benzalkonium chloride swab			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43269-959
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.1 mg in 1 mL
Inactive Ingredients			
<b>Ingredient Name</b>		<b>Strength</b>	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)			
WATER (UNII: 059QF0K00R)			
ALCOHOL (UNII: 3K9958V90M)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
Packaging			
#	Item Code	Package Description	Marketing Start Date Marketing End Date

1	NDC:43269-959-10	0.1 mL in 1 CANISTER; Type 0: Not a Combination Product	05/12/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	05/12/2020		

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Tonic Bath & Body Products Shenzhen Ltd		528 197042	manufacture(43269-959)

Revised: 5/2020

SJ Creations, Inc.