

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.

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, Didecyldimethylammonium Chloride, Exylhexylglycerin.

Package Label - Principal Display Panel



**Antibacterial
MOISTURIZING
HAND WIPES**


KILLS **99.99%**
OF GERMS

80 WIPES
(18CM x 20CM)

Drug Facts

Active ingredient Benzalkonium Chloride 0.1% v/v	Purpose Antiseptic
Use • Hand sanitizer to help reduce bacteria on the skin.	
Warnings For external use only. Flammable. Keep away from fire and flame. When using this product avoid contact with eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation and redness develop. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions • Wet hands thoroughly with product and allow to dry. • Children under 6 years of age should be supervised when using this product.	
Other information • Store at 20°C to 25°C (68°F to 77°F). • May discolor some fabrics or surfaces.	
Inactive ingredients Water (Aqua), Ethyl Alcohol, Glycerin, Propylene Glycol, Phenoxyethanol, Didecyldimethylammonium Chloride, Ethylhexylglycerin.	
Questions? 1-888-942-7280 Monday – Friday 9 AM – 5 PM PST	

201134
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PRODUCT OF CHINA



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80ct NDC: 43269-940-80

ANTIBACTERIAL WIPES			
benzalkonium chloride swab			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43269-940
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.1 mg in 1 mL
Inactive Ingredients			
Ingredient Name		Strength	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)			
WATER (UNII: 059QF0KO0R)			
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:43269-940-80	0.1 mL in 1 CANISTER; Type 0: Not a Combination Product	04/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - SJ Creations, Inc. (146379495)

Establishment

Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528 197042	manufacture(43269-940)

Revised: 5/2020

SJ Creations, Inc.