FROZEN COTTON CANDY- benzalkonium chloride gel Townley 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.

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use

To decrease bacteria on the skin that could cause disease

Directions

- Rub a dime sized drop into hands.
- For children under 6 use under adult supervision.

Warnings

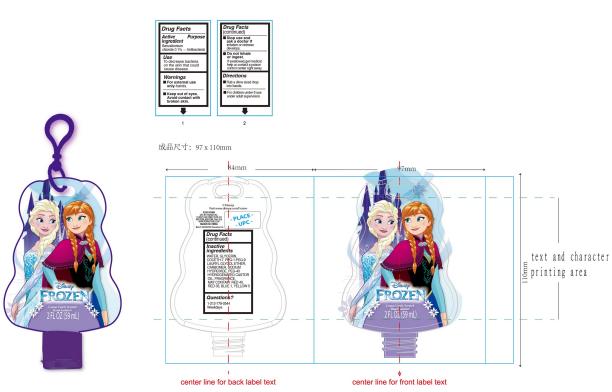
- For external use only hands.
- Keep out of eyes. Avoid contact with broken skin.
- **Stop use and ask a doctor if** irritation or redness develops.
- **Do not inhale or ingest.** If swallowed, get medical help or contact a poison control center right away.

keep out of reach of children

Inactive ingredients

water, glycerin, coceth-7, PPG-1-PEG-9 lauryl glycol ether, carbomer, sodium hydroxide, PEG-40 hydrogenated castor oil, fragrance, may contain: red 40, red 33, blue 1, yellow 5.





FROZEN COTTON CANDY

benzalkonium chloride gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58737-208	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)				
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
WATER (UNII: 059QF0KO0R)				

GLYCERIN (UNII: PDC6A3C0OX)	
CO CETH-7 (UNII: 58 Y26 1JLH5)	
PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:58737-208-01	59 g in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2017	

Labeler - Townley Inc. (016956158)

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Jinxiong Technology Co., Ltd.		544328419	manufacture(58737-208)	

Revised: 5/2017 Townley Inc.