

DISNEY FROZEN STRAWBERRY SANITIZER- benzalkonium chloride gel
Shenzhen Lantern Science Co., Ltd.

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.

Keep out of reach of children.

☐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.

☐Directions

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

☐Inactive Ingredients

water (aqua/eau), glycerin, coceth-7, PPG-1-PEG-9 lauryl glycol ether, carbomer, hydrogenated castor oil, fragrance (parfum).

☐May Contain

Red 40 (CI 16035), Red 33 (CI 17200), Blue 1 (CI 42090), Yellow 5 (CI 19140).

Hand Sanitizer

FZ0560SA

2016_05_09 (J)

— DIE LINE—DO NOT PRINT
 CMYK PROCESS
 CLEAN ADHESIVE STOCK
 DO NOT PRINT

Townley
 110-010 Avenue, Suite 1100
 New York, NY 10036
 Call (212) 779-0548 • Fax (212) 779-4992

**CONFIRM WEIGHTS +
 FLAVORS + WARNING
 White Base X2**



DISNEY FROZEN STRAWBERRY SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54860-048
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 g in 59 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CO CETH-7 CARBOXYLIC ACID (UNII: 35KO064932)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L)	

Product Characteristics

Color	red (red 40) , red (Red 33) , blue (Blue 1) , yellow (Yellow 5)	Score	
Shape		Size	
Flavor	BLUEBERRY, CHERRY, LEMON, BERRY, GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54860-048-01	59 g in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/17/2016	

Labeler - Shenzhen Lantern Science Co., Ltd. (421222423)**Establishment**

Name	Address	ID/FEI	Business Operations
Shenzhen Lantern Science Co., Ltd.		421222423	manufacture(54860-048)

Revised: 8/2016

Shenzhen Lantern Science Co., Ltd.