

**FROZEN BUBBLE GUM HAND 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 0.01%

☐

Purpose:☐ Antibacterial

☐ Use

To decrease bacteria on the skin that could cause disease.

Keep out of reach of children.

Frozen Bubble Gum Hand Sanitizer

2 FL OZ (59mL)

☐ 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), coceth-7, PPG-1-PEG-9 lauryl glycol ether, triethanolamine, PEG-40 hydrogenated castor oil, chloropropylate, fragrance (parfum).



FROZEN BUBBLE GUM HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54860-033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.01 g in 59 g

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCETH-7 CARBOXYLIC ACID (UNII: 35KO064932)	
CHLORO PROPYLATE (UNII: G103ROM7HQ)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54860-033-01	59 g in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/08/2016	

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

Name	Address	ID/FEI	Business Operations
shenzhen Lantern Science Co. Ltd.		421222423	manufacture(54860-033)