

**FROZEN GRAPE 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.*

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**☐ Active Ingredient**

Benzalkonium Chloride 0.01%

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

Frozen Grape Hand Sanitizer

2 FL OZ (59mL)



**FROZEN GRAPE HAND SANITIZER**

benzalkonium chloride gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54860-034
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54860-034-01	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	06/13/2016	

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

Name	Address	ID/FEI	Business Operations
shenzhen Lantern Science Co. Ltd.		421222423	manufacture(54860-034)