

BERRY SCENTED HAND SANITIZER CARS- 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

☐May Contain

Red 40 (CI 16035)

Red 33 (CI 17200)

Blue 1 (CI42045)

Yellow 5 (CI 19140)

☐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 etyher, carbomer, sodium hydroxide, peg-40 hydrogenated castor oil, fragrance/parfum.

CA0001SA

2015/03/04(b)

— DIE LINE—DO NOT PRINT

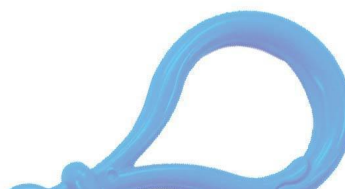
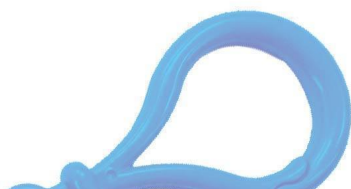


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FLAVORS + WARNING
White Base X2**

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Drug Facts

Active Ingredient
 BENZALKONIUM CHLORIDE 0.1%
Purpose:Antibacterial

Use
 To decrease bacteria on the skin that could cause disease.

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CA00015A
 - PLACE -
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 MADE IN CHINA
PEEL UP TO SEE ADDITIONAL DRUG FACTS

Drug Facts
 (continued)

Warnings

- For external use only-hands.
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Directions

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

Drug Facts
 (continued)

Inactive Ingredients
 WATER (AQUAVEAU), GLYCERIN, COCETH-7, PPG-1-PEG-9 LAURYL GLYCOL ETHER, CARBOMER, SODIUM HYDROXIDE, PEG-40 HYDROGENATED CASTOR OIL, FRAGRANCE (PARFUM).

May Contain
 RED 40 (CI 16035), RED 33 (CI 17200), BLUE 1 (CI 42090), YELLOW 5 (CI 19140).

Questions?
 1-212-779-0544
 Weekdays

Batch XXXXXXX Townley Inc

BERRY SCENTED HAND SANITIZER CARS

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54860-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.06 mg in 59 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCEETH-7 CARBOXYLIC ACID (UNII: 35KO064932)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY, BERRY, APPLE, RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54860-017-01	59 mg in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/29/2013	

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

Name	Address	ID/FEI	Business Operations
Shenzhen Lantern Science Co., Ltd.		421222423	manufacture(54860-017)