

BLUEBERRY SCENTED 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 0.1%

☐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, glycerin, coceth-7, PPG-1-PEG-9 lauryl glycol ether, carbomer, 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).

Hand Sanitizer

EA0019WA

2016_05_30 (b)

— DIE LINE—DO NOT PRINT

CMYK PROCESS

CLEAR ADHESIVE STOCK
DO NOT PRINT

Townley
380 Fifth Avenue, Suite 1100
New York, NY 10016
Call (212) 779-0544 • Fax (212) 779-4192

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



BLUEBERRY SCENTED HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54860-082

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 30 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
CO CETH-7 (UNII: 58Y261JLH5)	
CARBOXYMETHYL FRAGMENT (UNII: 0KIZ9B76US)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54860-082-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/24/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Shenzhen Lantern Science Co., Ltd.		421222423	manufacture(54860-082)

Revised: 4/2017

Shenzhen Lantern Science Co., Ltd.