

DESPICABLE ME BERRY- benzalkonium chloride gel

Townley Inc.

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

Directions

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

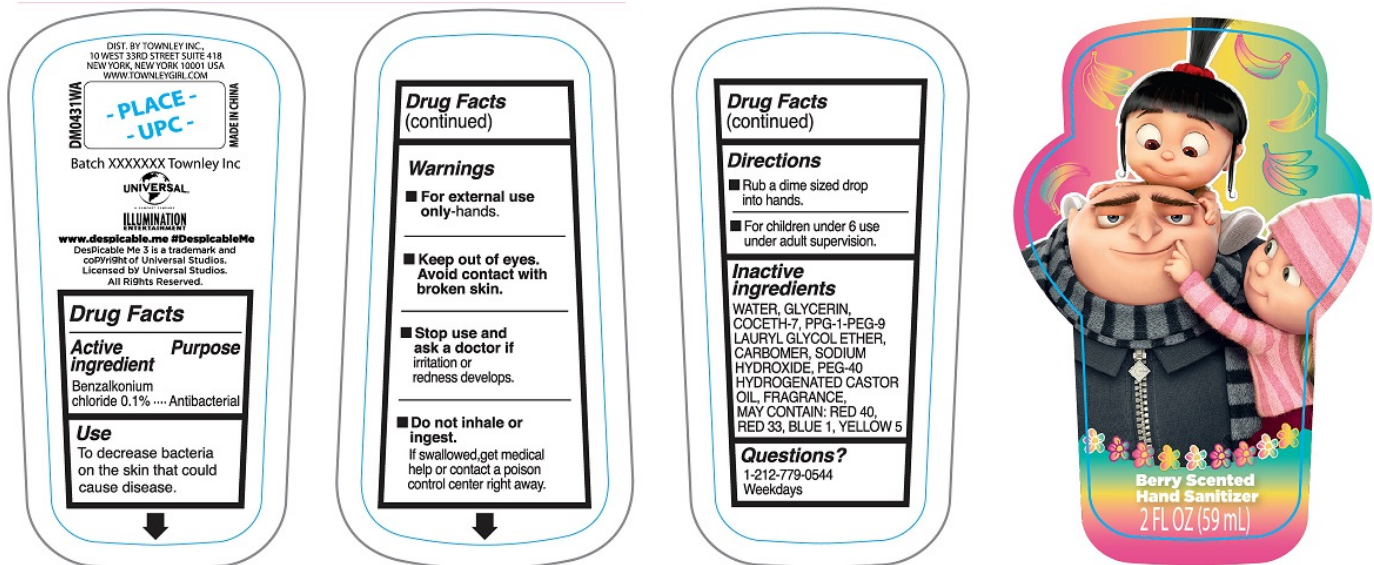
Warnings

- **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.

keep out of reach of children

Inactive ingredients

water, glycerin, coceth-7, PPG-1-PEG-9 lauryl glycol ether, carbomer, sodium hydroxide, PEG-40 hydrogenated castor oil, fragrance, may contain: red 40, red 33, blue 1, yellow 5.



DESPICABLE ME BERRY

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58737-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCEATH-7 (UNII: 58Y261JLH5)	
PPG-1-PEG-9 LAURYL GLYCOL ETHER (UNII: 5R8J43K25L)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58737-205-01	59 g in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/28/2017	

Labeler - Townley Inc. (016956158)**Establishment**

Name	Address	ID/FEI	Business Operations
Foshan Jinxiong Technology Co., Ltd.		544328419	manufacture(58737-205)

Revised: 4/2017

Townley Inc.