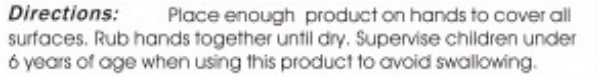
0.13% BENZALKONIUM CHLORIDE INSTANT HAND SANITIZER- hand sanitizer gel
BJ Goods LLC

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.

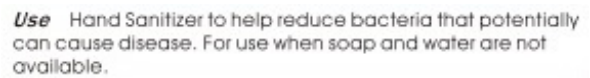
Keep out of reach of children


Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

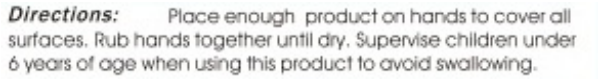

Directions: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

Use: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.


Use Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Dosage form: Gel

Directions: Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years of age when using this product to avoid swallowing.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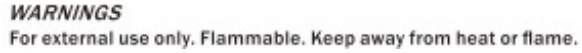
Benzalkonium Chloride 0.13% v/v


Active Ingredient	**Purpose**
Benzalkonium Chloride 0.13% v/v	Antiseptic

Warnings: For external use only. Flammable. Keep away from heat or flame.


WARNINGS
For external use only. Flammable. Keep away from heat or flame.

Do not use: In children less than 2 months of age. On open skin wounds.

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When using this product: Keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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Stop use and ask a doctor if: irritation or rash occurs. These may by signs o a serious condition.

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These may be signs of a serious condition.

Aloe, glycerin, sterile distilled water

Inactive ingredients
aloe, glycerin, sterile distilled water.

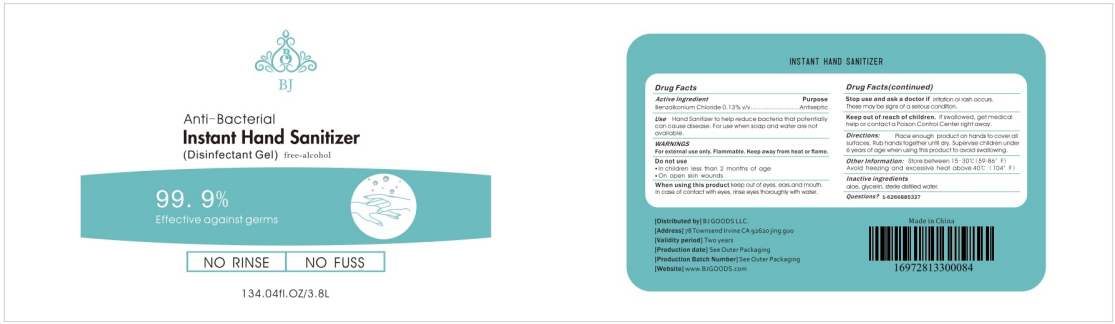
Anti-Bacterial Hand Sanitizer (Disinfectant Gel) free - alcohol

3.8L label NDC: 79635-019-05

3.8L

470mm

135mm

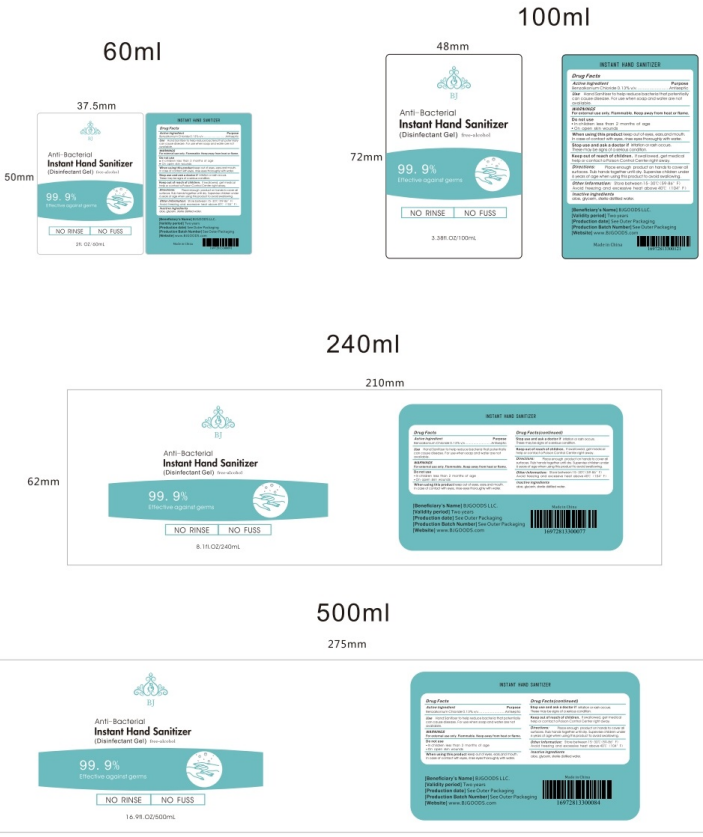


60 ml label NDC:79635-019-01

100 ml label NDC: 79635-019-02

240 ml label NDC: 79635-019-03

500 ml label NDC: 79635-019-04



0.13% BENZALKONIUM CHLORIDE INSTANT HAND SANITIZER

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79635-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.14 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	0.1 g in 100 mL
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	0.1 g in 100 mL

ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.09 g in 100 mL
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	0.5 g in 100 mL
WATER (UNII: 059QF0KO0R)	96.08 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79635-019-03	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	
2	NDC:79635-019-04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	
3	NDC:79635-019-01	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	
4	NDC:79635-019-05	3800 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	
5	NDC:79635-019-02	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/04/2020	

Labeler - BJ Goods LLC (117585173)

Revised: 7/2020 BJ Goods LLC