E3 ALCOHOL FREE FOAMING SANITIZER- benzalkonium chloride soap Betco Corporation, 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.

E3 Alcohol Free Foaming Sanitizer

Label faces wall

E3 Alcohol Free Foaming Sanitizer

Fast Drying, Moisturizing Hand Sanitizer for Food Service

Drug Facts

Active Ingredient

Purpose

Benzalkonium Chloride 0.1%Antimicrobial

Uses

- For hand sanitizing to decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

- For external use only.
- When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.
- Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Read the entire label before using this product.
- Dispense 2 pumps of product onto palm of hand and rub thoroughly over all surfaces of both hands until dry.

Inactive Ingredients

Water, cetrimonium chloride, laurtrimonium chloride, dihydroxyethyl cocamine oxide, glycereth-17 cocoate, citric acid.





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Progr (Registr

Program Listed (E3) (Registration No.149639)

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750 mL (25.4 fl. oz.) Item #779 SDS No. 779 RLB6540 0477916

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E3 ALCOHOL FREE FOAMING SANITIZER

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-779
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Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5 IBP)		
LAURTRIMO NIUM CHLO RIDE (UNII: A8 1MS 10 FIC)		
DIHYDRO XYETHYL CO CAMINE O XIDE (UNII: 8 AR51R3BL5)		
GLYCERETH-17 CO CO ATE (UNII: 3057VPT0KC)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65601-779-04	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 16	03/26/2019
2	NDC:65601-779-05	1200 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 16	

3 NDC:65601-779-03	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 16		
4 NDC:65601-779-29	1000 mL in 1 BAG; Type 0: Not a Combination Product	0 1/0 1/20 16		
Marketing Information				
Mai keting inioi mation				
Marketing Categor	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fir	nal part333A	0 1/0 1/20 16		

Labeler - Betco Corporation, Ltd. (024492831)

Registrant - Betco Corporation, Ltd. (024492831)

Establishment			
Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd.		024492831	manufacture(65601-779), pack(65601-779), label(65601-779), analysis(65601-779)

Revised: 3/2019 Betco Corporation, Ltd.