BSAFE INSTANT FOAMING HAND SANITIZER- benzalkonium chloride aerosol, foam
Med-Dev Corporation

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.

B'Safe Instant Foaming Hand Sanitizer with Conditioners

Active ingredient

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Uses

- For hand sanitizing to decrease bacteria on the skin
- Recommended for repeated use
- Significantly reduces bacteria on hands between regular hand washing but not intended to replace regular hand washing.

Warnings

For External use only.

When using this product avoid contact with eyes and nose. In case of contact flush eyes with water.

Stop use and consult a doctor if irritation or redness develops.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Pump small amount of foam into palm of hand. Rub thoroughly over all surfaces of both hands. Rub hands together briskly until dry.

Inactive ingredients

Purified Water, Glycerin, Dihydroxyethyl Cocamine Oxide, Dihydroxypropyl PEG-5 Linoleammonium Chloride, Glycereth-17 Cocoate, Cetrimonium Chloride, Laurtrimonium Chloride

Package/Label Principal Display Panel - Carton Label

B'Safe
Instant Foaming
Hand Sanitizer
with Conditioners

B'Safe B'Soft B'Sure

Alcohol Free
Odorless
Non Flammable

1000ml

Med-Dev Corporation
TekRidge Center, 50 Alberigi Dr., Suite 106, Jessup, PA 18434

570-383-6772

MADE IN THE USA

Carton Label

BSAFE INSTANT FOAMING HAND SANITIZER

benzalkonium chloride aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69348-100

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 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIHYDROXYETHYL COCAMINE OXIDE (UNII: 8AR51R3BL5)	
DIHYDROXYPROPYL PEG-5 LINOLEAMMONIUM CHLORIDE (UNII: 0Y0NQR2GH1)	
GLYCERETH-17 COCOATE (UNII: 3057VPT0KC)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69348-100-01	1000 mL in 1 POUCH; 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	12/04/2014	

Labeler - Med-Dev Corporation (053927573)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing, Inc.		793406000	MANUFACTURE(69348-100)

Revised: 12/2014 Med-Dev Corporation