

BEN E. KEITH FIHS- benzalkonium chloride solution

Ben E. Keith Foods

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.

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13% w/w

Purpose

Antibacterial Agent

Uses

Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

- For external use only
- Avoid contact with eyes

Avoid contact with eyes. If contact occurs, flush with water.

Stop use if, in rare instances, redness or irritation develop. If condition persists for more than 72 hours, consult a physician.

Keep out of reach of children. If swallowed, contact a physician or poison control center.

Directions

- To decrease bacteria on skin, apply small amount to palm. Briskly rub, covering hands with product until dry.

Inactive Ingredients Water, Propylene Glycol, Cocamidopropyl Betaine, Aloe Barbadensis Leaf, Tocopheryl Acetate (Vitamin E), PEG-7 Glyceryl Cocoate, Fragrance, Phenoxyethanol, Tetrasodium EDTA.

Representative label and principal display panel

ALCOHOL-FREE

BEN E. KEITH

ESSENTIALS

FOAMING

INSTANT HAND

SANITIZER

REORDER

#885610

Net Contents: 1000 mL (33.8 Fl. Oz.)

DISTRIBUTED BY Ben E. Keith Foods

FT. WORTH, TX 76101



ALCOHOL-FREE

ESSENTIALS

FOAMING INSTANT HAND SANITIZER

Higienizador Instantáneo
Espumoso para las Manos

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Ingrediente Activo Cloruro de benzalkonium 0.13% en peso (Agent antibacterial) **Usos** Se usa para el lavado de manos a fin de disminuir las bacterias en la piel. **Advertencias** Solamente para uso externo. No lo utilice en los ojos. En casos raros de irritación y enrojecimiento, suspenda el uso. Si el estado persiste durante más de 72 horas consulte con un médico. Si se ingiere llame a un médico o a un centro de control de venenos. Mantenga fuera del alcance de niños. **Modo de Empleo** Para disminuir las bacterias en la piel, aplique una pequeña cantidad en la palma. Frote cubriendo las manos con brio hasta que el producto se seque. **Ingredientes Inactivos** Agua, perfume, jugo de hoja de aloe barbadensis, acetato tocoferílico (vitamina E), betaina cocamidopropilica, propilén glicol, fenoxietanol, PEG-7 cocoato gliceril, tetrasodio de EDTA.

LAXXXXXX



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BEN E. KEITH FIHS

benzalkonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50980-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50980-207-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	05/31/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/31/2016	

Labeler - Ben E. Keith Foods (007929748)
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