

HEALTH GUARD ANTIBACTERIAL HAND CLEANSER F217F- benzalkonium chloride soap
Kutol Products Company

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 0.13% w/w

Ingrediente activo

Cloruro de benzalconio

☐Purpose

Antibacterial agent

Propósito

Agente antibacteriano

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

Manténgase fuera del alcance de los niños. Si se ingiere, consulte a un médico o contacte inmediatamente con un centro de control de envenenamiento.

☐Uses ☐ For handwashing to decrease bacteria on the skin.

Usos Para lavar las manos para disminuir las bacterias en la piel.

☐Directions

- Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse.

Direcciones

Aplique una pequeña cantidad, cubriendo las manos con el producto durante 30 segundos. Añada agua, espolvoree y enjuague

☐Inactive Ingredients

water, cetrimonium chloride, lauramine oxide, sorbitol, cocamide MEA, sodium chloride, PEG-120 methyl glucose dioleate, sodium lauraminodipropionate, citric acid, fragrance, disodium EDTA, methylothiazolinone, methylchloroisothiazolinone, blue 1.

Ingredientes inactivos

agua, cloruro de cetrimonio, óxido de lauramina, sorbitol, cocamida MEA, cloruro de sodio, PEG-120 metil diolato de glucosa, lauraminodipropionato de sodio, ácido cítrico, fragancia, EDTA disódico, metiisotiazolinona, metilcloroisotiazolinona, azul 1.

Warnings

For external use only.

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

Stop use and ask a doctor if in rare instances, redness and irritation develops and persists.

Advertencias

Sólo para uso externo.

Evitar el contacto con los ojos.

Deje de usar y consulte a un médico si en raras ocasiones se desarrolla y persiste enrojecimiento e

313-527-5500 fax blevenson@kutol.com	Printed on _____ white polyp	Printer - please put our formula number on your proof.
KUTOL INTERNAL	Formula 217F	
Approved _____	Item No. (Kutol use only) _____ MSC098201A	
Date _____	Revisions: 6/9/17 new	
Changes:		

HEALTH GUARD ANTIBACTERIAL HAND CLEANSER F217F

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50865-217
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.013 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
SORBITOL (UNII: 506T60A25R)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PEG-120 METHYL GLUCOSE DIOLATE (UNII: YM0K64F20V)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50865-217-65	800 mL in 1 BAG; Type 0: Not a Combination Product	09/29/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/29/2017	

Labeler - Kutol Products Company (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company		004236139	manufacture(50865-217)

Revised: 1/2019

Kutol Products Company