

FOAMING ADVANCED ANTIBACTERIAL HAND- 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.

F213F Foaming advanced antibacterial soap

☐Active Ingredient

Benzalkonium Chloride 0.13% w/w

☐Purpose

Antibacterial

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

☐Uses Handwash to help decrease bacteria on the skin

☐Directions To decrease bacteria on the skin, apply a small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

☐Warnings

For external use only. Avoid contact with eyes. If eye contact occurs, flush eyes with water.

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

☐Inactive Ingredients

water, cocamidopropyl betaine, cocamidopropyl PG-dimonium chloride phosphate, PEG-6 cocamide, laurtrimonium chloride, aloe barbadensis leaf juice, tocopheryl acetate (vitamin E), fragrance, iodopropynyl butylcarbamate, methylisothiazolinone, yellow 5, red 33.

KUTOL

Foaming Advanced Antibacterial Hand Soap

FORMULATED
WITHOUT TRICLOSAN

Drug Facts

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Directions To decrease bacteria on skin, apply a small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

Inactive Ingredients: Water, Cocamidopropyl Betaine, Cocamidopropyl PG-Dimonium Chloride Phosphate, PEG-6 Cocamide, Laurtrimonium Chloride, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), Fragrance, Iodopropynyl Butylcarbamate, Methylisothiazolinone, Yellow 5, Red 33.

KUTOL

Hand Hygiene Specialists
Cincinnati, Ohio 45241 www.kutol.com

Manufactured in the USA in a
LEED® Silver certified facility

Net Contents: 3.785 L (one gallon)

MG429KFA





use with
No Touch Dispenser



ezFOAM™
By KUTOL

Formulated without Triclosan

Foaming Advanced Antibacterial Hand Soap
with Aloe and Vitamin E

Savon à mains en mousse antibactérien avancé

Jabón de mano antibacterial con espuma de fórmula más avanzada

Drug Facts

Active Ingredient

Benzalkonium Chloride 0.13% w/w

Purpose

Antibacterial

Uses ■ For handwashing to decrease bacteria on skin.

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Directions

- To decrease bacteria on skin, apply small amount, covering hands with product for 30 seconds. Add water, lather, and rinse.

Inactive Ingredients

Water, Cocamidopropyl Betaine, Cocamidopropyl PG-Dimonium Chloride Phosphate, PEG-6 Cocamide, Laurtrimonium Chloride, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), Fragrance, Iodopropynyl Butylcarbamate, Methylisothiazolinone, Yellow 5, Red 33.

Ingrédient actif : chlorure de benzalkonium 0,13 % p/p (Agent antibactérien) **Utilisations** Pour le lavage des mains, afin de réduire les bactéries sur la peau. **Avvertissements** Pour usage externe seulement. Ne pas mettre dans les yeux. En cas d'irritation ou de rougeur, arrêtez l'utilisation. Si les symptômes persistent plus de 72 heures, consultez un médecin. En cas d'ingestion, consultez un médecin ou un centre antipoison. Garder hors de portée des enfants. **Mode d'emploi** Appliquer une quantité suffisante, se couvrant les mains pendant 30 secondes. Ajouter d'eau, former une mousse et rincer.

Ingrédients inactifs : eau, bétaine de cocamidopropyle, phosphate de chlorure de PG-dimonium de cocamidopropyle, PEG-6 cocamide, chlorure de laurtrimonium, jus de feuille d'Aloe Barbadensis, acétate de tocophérol (vitamine E), parfum, butylcarbamate d'iodopropynyle, méthylisothiazolinone, jaune 5, rouge 33.

Ingrediente Activo Cloruro de benzalconio 0.13 % en peso (Agentes antibacteriano) **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** Aplique una cantidad pequeña de producto sobre las manos, cubriendo las manos durante 30 segundos. Añada agua, forme espuma y enjuague. **Ingredientes Inactivos** Agua, Cocamidopropil betaina, Cloruro y Fosfato de Cocamidopropil PG-dimonio, PEG - 6 Cocamida, Cloruro de Laurtrimonio, Jugo de Hoja de Aloe Barbadensis, Acetato de tocoferol (Vitamina E), Fragancia, Yodopropiril Butilcarbamato, Metilisotiazolinona, Amarillo 5, Rojo 33.

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

Manufactured in the USA
in a LEED® Silver certified facility

MANUFACTURED BY:
KUTOL PRODUCTS COMPANY
CINCINNATI, OH 45241
1-800-543-4641 www.kutol.com

L45300



ezFOAM™
By KUTOL

Formulated without Triclosan

Foaming Advanced Antibacterial Hand Soap
with Aloe and Vitamin E

Savon à mains en mousse antibactérien, formule avancée
Jabón de mano antibacterial en espuma de fórmula más avanzada

Drug Facts

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Directions

- To decrease bacteria on skin, apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.

Inactive Ingredients Water, Cocamidopropyl Betaine, Cocamidopropyl PG-Dimonium Chloride Phosphate, PEG-6 Cocamide, Laurtrimonium Chloride, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), Fragrance, Iodopropynyl Butylcarbamate, Methylisothiazolinone, Yellow 5, Red 33.

Ingrediente activo : chlorure de benzalkonium 0.13 % p/p (Agent antibactérien) **Utilisations** Pour le lavage des mains, afin de réduire les bactéries sur la peau. **Avertissements** Pour usage externe seulement. Ne pas mettre dans les yeux. En cas d'irritation ou de rougeur, arrêtez l'utilisation. Si les symptômes persistent plus 72 heures, consultez un médecin. En cas d'ingestion, consultez un médecin ou un centre antipoison. Garder hors de portée des enfants. **Mode d'emploi** Appliquer une quantité suffisante, se couvrant les mains pendant 30 secondes. Ajouter d'eau, former une mousse et rincer. **Ingédients inactifs** : eau, bétaine de cocamidopropyle, phosphate de chlorure de PG-dimonium de cocamidopropyle, PEG-6 cocamide, chlorure de laurtrimonium, jus de feuille d'Aloe Barbadensis, acétate de tocophérol (vitamine E), parfum, butylcarbamate d'iodopropynyle, méthylisothiazolinone, jaune 5, rouge 33.

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

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MANUFACTURED BY:
KUTOL PRODUCTS COMPANY
CINCINNATI, OH 45241
1-800-543-4641 www.kutol.com

LAA1100

DESIGNER SERIES
1250 mL



Formulated without Triclosan

Foaming Advanced Antibacterial Hand Soap

with Aloe and Vitamin E

Savon à mains en mousse antibactérien, formule avancée

Jabón de mano antibacterial en espuma de fórmula más avanzada

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Net Contents: 1250 mL (42 Fl. Oz.)

Manufactured in the USA

in a LEED® Silver certified facility

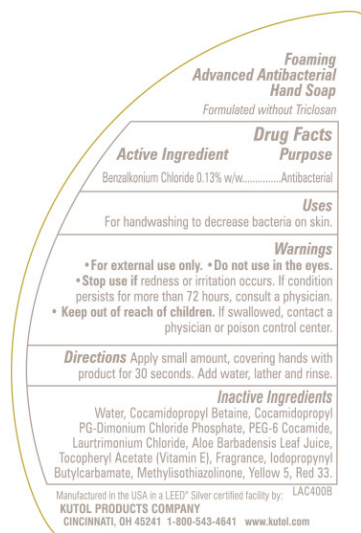
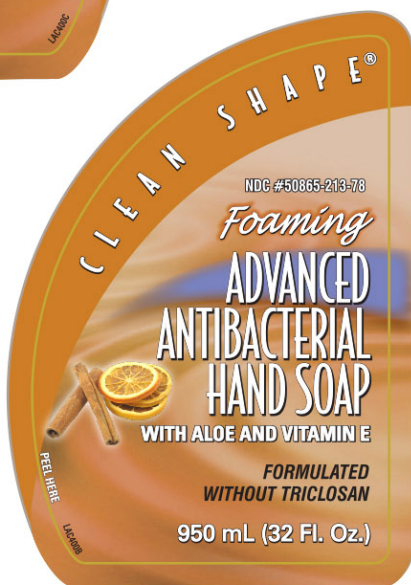
MANUFACTURED BY:

KUTOL PRODUCTS COMPANY

CINCINNATI, OH 45241

1-800-543-4641 www.kutol.com

LA410E



FOAMING ADVANCED ANTIBACTERIAL HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50865-213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.003 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
PEG-6 COCAMIDE (UNII: YZ6NLA4O1E)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50865-213-24	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	06/20/2017
2	NDC:50865-213-41	1000 mL in 1 BAG; Type 0: Not a Combination Product	10/01/2015	
3	NDC:50865-213-50	1200 mL in 1 BAG; Type 0: Not a Combination Product	10/01/2015	
4	NDC:50865-213-78	950 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	
5	NDC:50865-213-13	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	
6	NDC:50865-213-17	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	
7	NDC:50865-213-52	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/01/2015	

Labeler - Kutol Products Company (004236139)

Registrant - Kutol Products Company (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company		004236139	manufacture(50865-213)