#### FOAMING SANITIZING 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.

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#### F683F Foaming sanitizing 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** For handwashing to decrease bacteria on skin

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

**□Warnings** 

**For external use only. Do not use in the eyes.** If eye contact occurs, flush eyes with water.

**Stop use and ask a doctor if** redness and irritation occur and last for more than 72 hours.

## **||Inactive Ingredients|**

water, cocamidopropyl PG-dimonium chloride phosphate, cocamidopropyl betaine, PEG-6 cocamide, laurtrimonium chloride, iodopropynyl butylcarbamate, methylisothiazolinone.

STORE BETWEEN 33 TO 110F

# AMING E2 SANITIZING HAND SOAP

55 GALLON DRUM

**BATCH NUMBER:** 

MANUFACTURED BY:

**KUTOL PRODUCTS CO.** CINCINNATI, OH 45241 1.800.543.4641 www.kutol.com **MADE IN USA** 

ACTIVE INGREDIENT: BENZALKONIUM
CHLORIDE 0.13% W/W
OTHER INGREDIENTS: WATER, COCAMIDOPROPYL
PG - DIMONIUM CHLORIDE PHOSPHATE,
COCAMIDOPROPYL BETAINE, PEG - 6 COCAMIDE,
LAURTRIMONIUM CHLORIDE, IDDOPROPYNYL
BUTYLCARRAMATE, METHYLISOTHIAZOLINONE



#### Foaming E2 Sanitizing Hand Soap

Drug Facts	
Active ingredient	Purpose
Bergalkonium Chloride 0.13% w/w	Antibacterial
Uses For handwashing to decrease bac	teria on skirt.
Warnings	
For external use only. Do not use in th	eyes. If eye contact occurs, flush with water.
Stop use and ask a doctor if rechess ar	d imitation occur and last for more than 72 hours
Keep out of reach of children. If swallow	ved, contact a physician or poison control center
DI di constanti	ng hands with product for 30 seconds.





Foaming E2 Sanitizing Hand Soap

Mousse E2 Savon désinfectant pour les mains

E2 en Espuma Jabón para manos desinfectante

Net Contents / Contenu net / Contiendo neto: 3.785 L (one gallon) / 3,785 L / 3.785 L



Foaming E2 Sanitizing Hand Soap Assainissant Antibactérien Moussant pour les Mains E2 Higienizador Antibacterial Espumoso E2 para las Manos

# **Drug Facts**

#### **Active Ingredient**

**Purpose** 

Benzalkonium Chloride 0.13% w/w......Antibacterial Agent

**Uses** For handwashing to help reduce bacteria on the skin that could cause disease.

#### 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 or irritation develops and persists for more than 72 hours.
- **Keep out of reach of children.** If swallowed, contact a physician or poison control center.

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

**Inactive Ingredients** Water, Cocamidopropyl PG-Dimonium Chloride Phosphate, Cocamidopropyl Betaine, PEG-6 Cocamide, Laurtrimonium Chloride, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

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.
Avertissements Pour usage externe seulement. Ne pas mettre dans les yeux. En cas d'irritation, arrêtez l'utilisation en cas d'irritation ou de rougeur. 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 petite quantité, se couvrant les mains de produit pendant 30 secondes. Ajouter de l'eau, former une mousse et rincer. Ingrédients inactifs : eau, cocamidopropyl PG-dimonium chloride phosphate, bétaïne de cocamidopropyle, PEG-6 cocamide, laurtrimonium chloride, butylcarbamate d'iodopropynyle, méthylisothiazolinone.

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, suspenda el uso si se causa irritación y enrojecimiento. 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. Mode 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, Cloruro y Fosfato de Cocamidopropil PG- dimonio, Cocamidopropil Betaína, PEG - 6 Cocamida, Cloruro de Laurtrimonio, Yodopropinil Butilcarbamato, Metilisotiazolinona.

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





Foaming E2 Sanitizing Hand Soap cleans and kills common germs. Must be rinsed.

# Drug Facts

#### Active Ingredient Benzalkonium Chloride 0.13% w/w.

Purpose Antibacterial ..Agent

Uses

■ For handwashing to decrease bacteria on skin.

#### Warnings

### For external use only.

■Do not use in the eyes. If contact occurs, rinse eyes with water. - Stop use if redness or irritation occurs. If condition persists for more than 72 hours, consult a physician. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.

#### Directions

Apply a small amount of product to hands. Add water, work into a lather. Rinse thoroughly with potable water and dry.

Inactive Ingredients Water, Cocamidopropyl PG-Dimonium Chloride Phosphate, Cocamidopropyl Betaine, PEG-6 Cocamide, Laurtrimonium Chloride, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

Manufactured in the USA in a LEED®

KUTOL PRODUCTS CO., CINCINNATI, OH 45241 www.kutol.com

# **FOAMING SANITIZING HAND**

benzalkonium chloride soap

### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50865-683
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**Route of Administration** TOPICAL

ı	Active Ingredient/Active Moiety				
ı	Ingredient Name	<b>Basis of Strength</b>	Strength		
		BENZALKONIUM CHLORIDE	0.003 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)			
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)			
PEG-6 COCAMIDE (UNII: YZ6NLA4O1E)			
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)			
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50865- 683-03	4000 mL in 1 DRUM; Type 0: Not a Combination Product	10/01/2015	06/10/2017		
2	NDC:50865- 683-41	1000 mL in 1 BAG; Type 0: Not a Combination Product	10/01/2015			
3	NDC:50865- 683-78	950 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	06/10/2017		
4	NDC:50865- 683-44	1000 mL in 1 BAG; Type 0: Not a Combination Product	06/12/2016			
5	NDC:50865- 683-17	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2016			
6	NDC:50865- 683-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	06/12/2017			
7	NDC:50865- 683-09	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2015	06/12/2016		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/01/2015	

# Labeler - Kutol Products Company (004236139)

# Registrant - Kutol Products Company (004236139)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Kutol Products Company		004236139	manufacture(50865-683)	

Revised: 8/2023 Kutol Products Company