

# ANTIBACTERIAL HAND CLEANSER- 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

### Purpose

Antibacterial Handwashing

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

**Uses** Handwash to decrease bacteria on the skin.

### Directions

- Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse.
- Children under 6 years of age should be supervised when using this product.

### Warnings

**For external use only.**

**Do not use in the eyes.** In case of contact, immediately flush with water.

**Stop use and ask a doctor if** redness and irritation appears and lasts.

### Inactive Ingredients

water, cetrimonium chloride, lauramine oxide, sorbitol, cocamide MEA, sodium chloride, PEG-120 methyl glucose dioleate, sodium lauraminodipropionate, citric acid, fragrance, disodium EDTA, methylisothiazolinone, methylchloroisothiazolinone, yellow 5, red 33

#### Antibacterial Hand Soap

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Benzalkonium Chloride 0.13% w/w	Antibacterial Handwashing
<b>Uses</b> For handwashing to decrease bacteria on skin.	
<b>Warnings</b>	
For external use only.	
Do not use in the eyes. In case of contact, flush with water.	
Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours.	
Keep out of reach of children. If swallowed, contact a physician or poison control center.	
<b>Directions</b> To decrease bacteria on skin, apply small amount, covering hands with product for 30 seconds. Add water, lather, and rinse.	
<b>Inactive Ingredients</b> Water, Cetrimonium Chloride, Lauramine Oxide, Sorbitol, Cocamide MEA, Sodium Chloride, PEG-120 Methyl Glucose Dioleate, Sodium Lauraminodipropionate, Citric Acid, Fragrance, Disodium EDTA, Methylisothiazolinone, Methylchloroisothiazolinone, Yellow 5, Red 33.	

Manufactured in the USA by /  
Fabrique aux Etats-Unis par / Hecho en EE.UU. por

**KUTOL**  
Hand Hygiene Specialists  
KUTOL PRODUCTS CO.  
Cincinnati, Ohio 45241 www.kutol.com

Kutol is a LEED® Silver certified facility  
Kutol est un établissement certifié LEED® argent  
Kutol es un centro certificado LEED® plata



#### Savon antibactérien pour les mains

**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.  
**MODE D'EMPLOI :** Appliquer une petite quantité, se couvrir les mains de produit pendant 30 secondes. Ajouter de l'eau, former une mousse et rincer.  
**AVERTISSEMENTS :** Pour usage externe seulement. Ne pas introduire dans les yeux. En cas de contact avec les yeux, rincer avec de l'eau. Dans les rares occasions d'irritation, arrêter l'utilisation. Si la condition persiste plus de 72 heures, consultez un médecin. En cas d'ingestion, contactez un médecin ou un centre antipoison. Garder hors de la portée des enfants.  
**INGRÉDIENTS INACTIFS :** Eau, chlorure de cetrimonium, oxyde de lauramine, sorbitol, monoéthanolamine de cocamide, chlorure de sodium, PEG-120 (Diolate de méthylglucose, Lauramidodipropionate de sodium, Acide citrique, parfum, EDTA, disodique, méthylisothiazolinone, méthylchloroisothiazolinone, jaune 5, rouge 33.

#### Jabón antibacterial para manos

**INGREDIENTE ACTIVO:** Cloruro de benzalkonio 0.13 % en peso (Agente antibacteriano)  
**USOS:** Se usa para el lavado de manos a fin de disminuir las bacterias en la piel.  
**MODOS DE EMPLEO:** Para disminuir las bacterias en la piel, aplique una cantidad pequeña de producto sobre las manos, cubriendo las manos durante 30 segundos. Añada agua, forme espuma y enjuague.  
**ADVERTENCIAS:** Para uso externo solamente. No use en los ojos. Si entra en contacto con los ojos, enjuague con agua. En casos raros en que se produce irritación o enrojecimiento, deje de usarlo. Si la condición se mantiene durante más de 72 horas, consulte al médico. Si se lo traga, contacte al médico o al centro de control de venenos. Manténgalo alejado del alcance de los niños.  
**INGREDIENTES INACTIVOS:** Agua, cloruro de cetrimonio, óxido de lauramina, sorbitol, monoetanolamina de cocamide, cloruro de sodio, PEG-120 diolato de metil glucosa, Lauramidodipropionato de sodio, ácido cítrico, fragancia, EDTA disódico, Metilcloroisotiazolinona, metilisotiazolinona, amarillo 5, rojo 33.

### SOFT SILKY

Antibacterial Hand Soap

**Soft & Silky** antibacterial hand soap is effective against a wide range of bacteria. Mild yet effective, it helps protect your skin while it cleans.

**Drug Facts**

Active ingredient	Purpose
Benzalkonium Chloride 0.13% w/w	Antibacterial Handwashing

**Uses**

- Handwash to help decrease bacteria on the skin.

**Warnings**  
For external use only.

Do not use in the eyes. In case of contact, immediately flush with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse.
- Children under 6 years of age should be supervised when using this product.

**Inactive Ingredients**  
Water, Cetrimonium Chloride, Lauramine Oxide, Sorbitol, Cocamide MEA, Sodium Chloride, PEG-120 Methyl Glucose Dioleate, Sodium Lauramidopropionate, Citric Acid, Fragrance, Disodium EDTA, Methylisothiazolinone, Methylchlorisothiazolinone, Yellow 5, Red 33.

# SOFT SILKY

DO NOT OPEN BOX  
Pull out perforated panel on front to remove tube.  
NO ABRIR LA CAJA  
Para sacar el tubo, retire el panel perforado frontal.  
NE PAS OUVRIER LA BOITE  
Tirer sur le panneau perforé de l'avant pour sortir le tube.

## Antibacterial Hand Soap

NDC 50865-215-12

### SOFT SILKY

Le Savon antibactérien pour les mains contient du trichlosane, ingrédient prouvé efficace pour combattre les bactéries. Doux mais efficace, le Savon antibactérien pour les mains aide à protéger la peau tout en la nettoyant.

**INGRÉDIENT ACTIF:** chlorure de benzalkonium 0.13 % p/p

**MODE D'EMPLOI/INDICATIONS:** Pour réduire les bactéries sur la peau, appliquez une quantité suffisante couvrant les mains. Ajoutez de l'eau, formez une mousse et rincez.

**AVERTISSEMENTS:** Pour usage externe seulement. Ne pas mettre dans les yeux. En cas d'irritation, arrêtez l'utilisation. Si les symptômes persistent, consultez un médecin. En cas d'ingestion, consultez un médecin ou un centre antipoison. Gardez hors de portée des enfants.

**AUTRES INGRÉDIENTS:** Eau, chlorure de cetrimonium, oxyde de lauramine, sorbitol, méthylchlorisothiazolinone, chlorure de sodium, PEG-120, Dioleate de méthylglucose, lauramidopropionate de sodium, Acide citrique, parfum, EDTA disodique, méthylisothiazolinone, méthylchlorisothiazolinone, jaune 5, rouge 33.

El Jabón antibacteriano para las manos contiene trichlosano, ingrediente de probado eficacia contra las bacterias. Suave pero eficaz, el Jabón antibacteriano para las manos ayuda a proteger la piel al limpiarla.

**INGREDIENTE ACTIVO:** Cloruro de benzalcónio 0.13 % en peso

**MODE DE EMPLEO/INDICACIONES:** Para disminuir las bacterias sobre la piel, aplique una cantidad suficiente cubriendo las manos. Añada agua, forme una espuma y enjuague.

**ADVERTENCIAS:** Solamente para uso externo. No lo utilice en los ojos. En caso raro de irritación, suspenda el uso. Si el estado persiste, consulte con un médico. Si se ingiere lome a un médico o a un centro de control de venenos. Mantenga fuera del alcance de niños.

**CIROS INGREDIENTES:** Agua, cloruro de cetrimonio, óxido de lauramina, sorbitol, metilcloruro de sodio, PEG-120 dióleato de metil glucosa, lauramidopropionato de sodio, ácido cítrico, fragancia, EDTA disódico, Metilisotiazolinona, metilcloruroisotiazolinona, amarillo 5, rojo 33.

Manufactured in the USA in a LEED® Silver certified facility.

**KUTOL PRODUCTS CO.**  
Cincinnati, OH 45241  
1-800-543-4641 www.kutol.com  
Net Contents 1200mL (40.5 Fl. Oz.)  
Contenido líquido 1200 mL  
Contenido neto 1200 mL

### Loading Instructions

1. Pull out the perforated panel on the front of the box.
2. Push the tube into the box until it is fully seated.
3. Close the box by folding the top flap down.
4. The tube is now ready for use.

NDC 50865-215-19

# KUTOL

## ANTIBACTERIAL HAND SOAP

237 mL (8 Fl. Oz.)

LAM1456D

Mild yet effective, Kutol Antibacterial Soap helps protect your skin while it cleans.

<p><b>Drug Facts</b></p> <table border="1" style="width: 100%;"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Benzalkonium Chloride 0.13% w/w</td> <td>Antibacterial Agent</td> </tr> </tbody> </table> <p><b>Uses</b> ■ For handwashing to decrease bacteria on skin.</p> <p><b>Warnings</b> For external use only. Do not use in the eyes.</p> <p><b>Discontinue use</b> if redness and irritation develop. If condition persists for more than 72 hours, consult a physician.</p> <p><b>Keep out of reach of children.</b> If swallowed, contact a physician or poison control center.</p>	Active ingredient	Purpose	Benzalkonium Chloride 0.13% w/w	Antibacterial Agent	<p><b>Directions</b> Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse.</p> <p><b>Inactive ingredients:</b> Water, Cetrimonium Chloride, Lauramine Oxide, Sorbitol, Cocamide MEA, Sodium Chloride, PEG-120 Methyl Glucose Dioleate, Sodium Lauramidopropionate, Citric Acid, Fragrance, Disodium EDTA, Methylisothiazolinone, Methylchlorisothiazolinone, Yellow 5, Red 33.</p> <p style="text-align: right;">LAM1456E</p> <p><b>KUTOL</b> Cincinnati, OH Hand Hygiene Specialists 1-800-543-4641 www.kutol.com</p> <p>Made in the USA in a LEED® Silver certified facility</p>
Active ingredient	Purpose				
Benzalkonium Chloride 0.13% w/w	Antibacterial Agent				



**Antibacterial Skin Cleanser**

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Benzalkonium Chloride 0.13% w/w.....	Antibacterial
<b>Uses</b>	
• For handwashing to decrease bacteria on skin.	
<b>Warnings</b>	
• For external use only. • Do not use in the eyes.	
• Stop use if, in rare instances, irritation and redness 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.	
<b>Directions</b> Wet hands, apply a small amount of product and work into a lather for 20 seconds, rinse thoroughly, dry hands completely.	
<b>Inactive Ingredients</b>	
Water, Cetrimonium Chloride, Lauramine Oxide, Sorbitol, Cocamide MEA, Sodium Chloride, PEG-120 Methyl Glucose Dioleate, Sodium Lauraminodipropionate, Citric Acid, Fragrance, Disodium EDTA, Methylisothiazolinone, Methylchlorisothiazolinone, Yellow 5, Red 33.	
<b>Net Contents: 2000mL (67.6 fl. oz.)</b>	LAD701P
Manufactured in the USA in a LEED® Silver certified facility by:	
<b>KUTOL</b>	
Hand Hygiene Specialists Cincinnati, OH / 1-800-543-4641 / www.kutol.com	

## ANTIBACTERIAL HAND CLEANSER

benzalkonium chloride soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50865-215
<b>Route of Administration</b>	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)	
SODIUM LAURIMINODIPROPIONATE (UNII: 7G447D0DH9)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

PEG-120 METHYL GLUCOSE DIOLEATE (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:50865-215-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/17/2017	
2	NDC:50865-215-12	1200 mL in 1 BAG; Type 0: Not a Combination Product	08/17/2017	
3	NDC:50865-215-19	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/17/2017	
4	NDC:50865-215-65	800 mL in 1 BAG; Type 0: Not a Combination Product	08/17/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/17/2017	

**Labeler** - Kutol Products Company (004236139)

### Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company		004236139	manufacture(50865-215)

Revised: 1/2019

Kutol Products Company