

FOAMING INSTANT HAND SANITIZER WITH ALOE AND VITAMIN E- foaming instant hand sanitizer with aloe and vitamin e solution

Kutol Products Company, Inc.

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.

Foaming Instant Hand Sanitizer with Aloe and Vitamin E

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

Water, Fragrance, Aloe Barbadosis Leaf, Tocopheryl Acetate, Cocamidopropyl Betaine, Propylene Glycol, Phenoxyethanol, PEG-7 Glyceryl Cocoate, Tetrasodium EDTA.

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

For external use only.

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.

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

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68241

ezFOAM™ **No Alcohol**
By KUTOL *Foaming Instant Hand Sanitizer*
with Aloe and Vitamin E

Assainissant Instantané Moussant pour les Mains
Higienizador Instantáneo Espumoso para las Manos

Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride 0.13% w/w	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. 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 Apply a small amount to palm. Briskly rub, covering hands with product until dry.

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

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 de contact avec les yeux, rincer avec de l'eau. En cas rares d'irritation, 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** Pour réduire les bactéries sur la peau, appliquer une petite quantité sur la paume. Appliquer et faire pénétrer dans la peau en frottant. **Ingrédients inactifs** Eau, propylène glycol, bétaine cocamidopropylque, jus de feuille d'aloès barbadine, acétate tocophérylique (vitamine E), PEG-7 cocoate glycérylique, parfum, phénoxyéthanol, tétrasodium d'EDTA.

Ingrediente Activo Cloruro de benzalkonium 0.13% en peso (Agente 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. Si entra en contacto con los ojos, enjuáguelos con agua. En casos raros de irritación, 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. **Mode 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, propilén glicol, betaina cocamidopropilica, jugo de hoja de aloe barbadensis, acetato tocoferilico (vitamina E), PEG-7 cocoato gliceril, perfume, fenoxietanol, tetrasodio de EDTA.

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

68291

 <p>Kills 99.99% of common germs that can cause illness</p> <p>No Alcohol</p> <p>HAND SANITIZER E3 use without water</p> <ul style="list-style-type: none"> • Non-flammable • Non-drying to hands • Easy soft rub-in <p><i>with skin conditioners including Aloe and Vitamin E</i></p> <p>NET CONTENTS 18 Fl. Oz. (532 mL)</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Benzalkonium Chloride 0.13% w/w</td> <td>Antibacterial Agent</td> </tr> </table> <p>Uses ■ Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.</p> <p>Warnings</p> <ul style="list-style-type: none"> • For external use only. • 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. <p>Directions • Apply a small amount to palm. Briskly rub, covering hands with product until dry. • Children should be supervised when using this product.</p> <p>Inactive Ingredients Water, Propylene Glycol, Cocamidopropyl Betaine, Aloe Barbadosensis Leaf Juice, Tocopheryl Acetate (Vitamin E), PEG-7 Glyceryl Cocoate, Fragrance, Phenoxyethanol, Tetrasodium EDTA.</p> <p>KUTOL <small>Hand Hygiene Specialists</small></p> <p><small>Manufactured in the USA in a LEED® Silver certified facility by</small> KUTOL PRODUCTS CO., CINCINNATI OH 45241 1-800-543-4641 www.kutol.com</p>	Active Ingredient	Purpose	Benzalkonium Chloride 0.13% w/w	Antibacterial Agent	 <p>Kills 99.99% of common germs that can cause illness</p> <p>No Alcohol</p> <p>HAND SANITIZER E3 use without water</p> <ul style="list-style-type: none"> • Non-flammable • Non-drying to hands • Easy soft rub-in <p><i>with skin conditioners including Aloe and Vitamin E</i></p> <p>NET CONTENTS 18 Fl. Oz. (532 mL)</p>
Active Ingredient	Purpose					
Benzalkonium Chloride 0.13% w/w	Antibacterial Agent					

68250

DESIGNER SERIES
1250 mL



No Alcohol
Foaming Instant Hand Sanitizer *with Aloe and Vitamin E*
Assainissant Instantané Moussant pour les Mains
Higienizador Instantáneo Espumoso para las Manos
Kills 99.99% of common germs in 15 seconds

Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride 0.13% w/w	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. 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 Apply small amount to palm. Briskly rub, covering hands with product until dry.

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

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 de contact avec les yeux, rincer avec de l'eau. En cas rares d'irritation, 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** Pour réduire les bactéries sur la peau, appliquer une petite quantité sur la paume. Appliquer et faire pénétrer dans la peau en frottant.

Ingredients inactifs Eau, propylèneglycol, bétaine cocamidopropylique, jus de feuille d'aloès barbadine, acétate tocophérylique (vitamine E), PEG-7 cocoate glycérylique, parfum, phénoxyéthanol, tétrasodium d'EDTA.

Ingrediente Activo Cloruro de benzalkonium 0.13% en peso (Agente 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. Si entra en contacto con los ojos, enjuáguelos con agua. En casos raros de irritación, 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. **Mode 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, propilén glicol, betaina cocamidopropilica, jugo de hoja de aloe barbadensis, acetato tocoferílico (vitamina E), PEG-7 cocoato gliceril, perfume, fenoxietanol, tetrasodio de EDTA.

MANUFACTURED BY: **KUTOL PRODUCTS COMPANY**
CINCINNATI, OH 45241

Manufactured in the USA
in a LEED® Silver certified facility

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

NO ALCOHOL
Foaming Instant Hand Sanitizer
 E3 use without water • Kills 99.9% of common germs
 Just rub into hands

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.	
Warnings For external use only. Avoid contact with eyes. If contact occurs, flush eyes 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 Apply small amount to palm. Briskly rub, covering hands with product until dry.	
Inactive Ingredients Water, Propylene Glycol, Cocamidopropyl Betaine, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), PEG-7 Glyceryl Cocoate, Fragrance, Phenoxyethanol, Tetrasodium EDTA.	

Manufactured in the USA by /
 Fabriqué aux États-Unis par / Hecho en E.E.U.U. 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



KUTOL



NO ALCOHOL
**Foaming Instant
 Hand Sanitizer**

with Aloe and Vitamin E

SANS ALCOOL
**Assainissant instantané
 moussant pour les mains**

avec aloé et vitamine E

SIN ALCOHOL
**Higienizador Instantáneo
 Espumoso para las Manos**

con Aloe y Vitamina E

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

SANS ALCOOL
Assainissant instantané moussant pour les mains
 Utilisation de l'E3 sans eau • Tue 99,9% des microbes ordinaires
 Il suffit de frotter le produit dans les mains.

Ingredient actif Chlorure de benzalkonium 0.13% w/w (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 de contact avec les yeux, rincer avec de l'eau. En cas d'irritation ou de rougeur, arrêter 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 petite quantité sur la paume. Appliquer et faire pénétrer dans la peau en frottant.

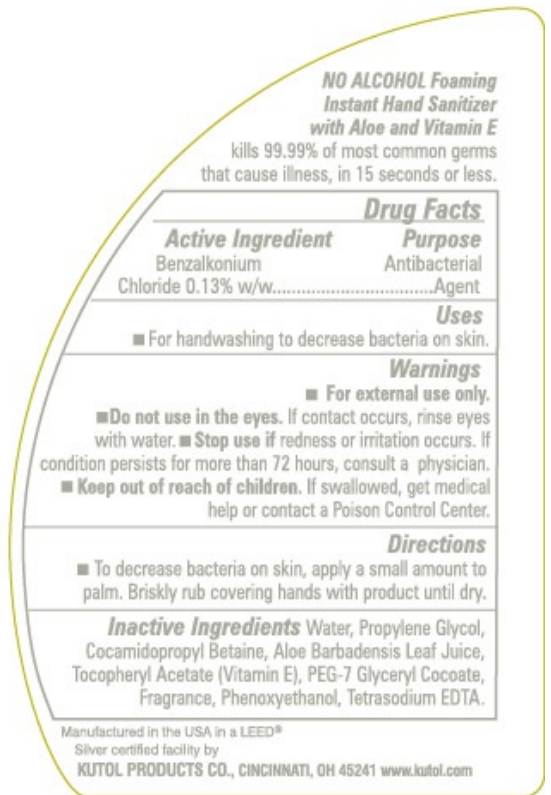
Ingédients inactifs Eau, propylène glycol, bétaïne cocamidopropyle, jus de feuille d'aloé barbadensis, acétate tocophérolique (vitamine E), PEG-7 cocoate glycérol, parfum, phénoxyéthanol, tétrasodium EDTA.

SIN ALCOHOL
Higienizador Instantáneo Espumoso Para Las Manos
 E3 se utiliza sin agua • Elimina el 99,9% de los gérmenes comunes.
 Simplemente frótelos en sus manos.

Ingrediente Activo Cloruro de benzalkonium 0.13% w/w (Agente antibacteriano)
Uses 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. Si entra en contacto con los ojos, enjuáguelos con agua. En casos raros de irritación y enrojecimiento, suspenda el uso. Si el estado persiste durante más de 72 horas consulte con un médico. Manténgala fuera del alcance de niños. Si se ingiere llame a un médico o a un centro de control de venenos.
Mode de Empleo Aplique una pequeña cantidad en la palma. Frote cubriendo las manos con brío hasta que el producto se seque.

Ingredientes inactivos Agua, propilén glicol, betaina cocamidopropilica, Jugo de hoja de aloé barbadensis, acetato tocoferolico (vitamina E), PEG-7 cocoato gliceri, perfume, tenosolol, tetrasodio de EDTA.

668278



68217



CONTAINS NO ALCOHOL

Drug Facts

Active Ingredient	Purpose
Benzalkonium Chloride 0.13% w/w	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. If contact occurs, flush with water. ■ Stop use and ask a doctor if, in rare instances, redness or irritation develops and persists for over 72 hours. ■ Keep out of reach of children. If swallowed, get medical help or contact a poison control center.

Directions

■ To decrease bacteria on skin, apply small amount of product to palms. Briskly rub, covering hands with product until dry.

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

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CINCINNATI, OH 45241 1-800-543-4641 www.kutol.com

FOAMING INSTANT HAND SANITIZER WITH ALOE AND VITAMIN E

foaming instant hand sanitizer with aloe and vitamin e solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50865-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 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:50865-207-03	208175 mL in 1 DRUM; Type 0: Not a Combination Product	05/31/2016	
2	NDC:50865-207-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
3	NDC:50865-207-17	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
4	NDC:50865-207-24	1000 mL in 1 BAG; Type 0: Not a Combination Product	05/31/2016	
5	NDC:50865-207-31	1000 mL in 1 BAG; Type 0: Not a Combination Product	05/31/2016	
6	NDC:50865-207-41	1000 mL in 1 BAG; Type 0: Not a Combination Product	05/31/2016	
7	NDC:50865-207-78	950 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2016	
8	NDC:50865-207-91	532 mL in 1 BOTTLE, PLASTIC; 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	part333A	05/31/2016	

Labeler - Kutol Products Company, Inc. (004236139)**Establishment**

Name	Address	ID/FEI	Business Operations
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Kutol Products Company, Inc.	004236 139	manufacture(50865-207) , analysis(50865-207) , label(50865-207) , pack(50865-207)
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Revised: 1/2019

Kutol Products Company, Inc.