

FOAMING ANTIBACTERIAL HAND WASH- benzalkonium chloride solution Global Equipment 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.

Global Equipment F213F

Active Ingredient - Benzalkonium Chloride

Purpose - Antibacterial

Uses - For handwashing to decrease bacteria on skin.

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 develop and persists for more than 72 hours.

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

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

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

GLOBAL
globalindustrial.com

**Advanced Antibacterial
Foam Hand Soap**

Reorder No. 641159 Savon à mains en mousse
Net Contents antibactérien, formule avancée
1200 mL (40.6 Fl. Oz.) Jabón de mano antibacterial en
 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.	
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 develop and persists for more than 72 hours. ■ Keep out of reach of children. If swallowed, contact a physician or poison control center.	
Directions Apply small amount, covering hands with product for 30 seconds. Add water, lather, rinse.	
Inactive Ingredients Water, Laurtrimonium Chloride, Cocamidopropyl Betaine, PEG-6 Cocamide, Cocamidopropyl PG-Dimonium Chloride Phosphate, Fragrance, Methylisothiazolinone, Iodopropynyl Butylcarbamate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), Yellow 5, Red 33.	

LA120V

Ingrediente activo: Cloruro de benzalkonio 0,13 % p/p (antibacteriano) **Utilizaciones** Pour le lavage des mains,


ann de require les bacteries sur la peau. **Avertissements** Pour usage externe seulement. Ne pas mettre dans les yeux. En cas de contact avec les yeux, rincer avec l'eau. 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, chlorure de laurtrimonium, bétaine de cocamidopropyle, PEG-6 cocamide, phosphate de chlorure de PG-dimonium de cocamidopropyle, parfum, méthylisothiazolinone, butylcarbamate d'iodopropynyle, jus de feuille d'aloe barbadensis, acétate de tocophérol (vitamine E), jaune 5, rouge 33.

Ingrediente Activo Cloruro de benzalconio 0.13 % en peso (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 y enrojecimiento, suspenda el uso. Si el estado persiste durante más de 72 horas consulte con un médico. Mantenga fuera del alcance de niños. Si se ingiere llame a un médico o a un centro de control de venenos. **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, Cloruro de Laurtrimonio, Cocamidopropil betaina, PEG-6 Cocamida, Cloruro y Fosfato de Cocamidopropil PG- dimonio, Fragancia, Metilisotiazolinona, Yodopropinil Butilcarbamato, Jugo de Hoja de Aloe Barbadensis, Acetato de tocoferol (Vitamina E), Amarillo 5, Rojo 33.

Made in the USA

Emergency:
Chemtrec 800-424-9300

Manufactured for:
Global Industrial
2505 Mill Center Parkway / Buford, GA 30518
For Reorders: 800-645-1232 / globalindustrial.com

 <p>KUTOL Hand Hygiene Specialists</p> <p>513-527-5500 513-527-5506 fax blevenson@kutol.com</p>	<p>Label No. <u>LAA120V</u></p> <p>Size <u>3 x 5</u> <u>Unwind</u></p> <p>Colors <u>PMS 2755 purple, 375 green, Process blue</u></p> <p>Printed on _____</p>
	<p>Formula <u>213F</u> Printer - please put our formula number on your proof.</p> <p>Item No. (Kutol use only) <u>641159</u></p> <p>Revisions: 10/18/16 - New item 7/7/17 - Improved formula 213F, remove "agent" from purpose in foreign language, change LA no. (OLD: LAA116D) 7/25/19 - Changing from 1250 mL to 1200 mL, (OLD LAA102L)</p>
<p>KUTOL INTERNAL</p> <p>Approved _____</p> <p>Date _____</p> <p>Changes:</p>	

Primary Label

FOAMING ANTIBACTERIAL HAND WASH

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78641-213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
LAURTRIMONIUM CHLORIDE (UNII: A81MSI0FIC)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
PEG-6 COCAMIDE (UNII: YZ6NLA4O1E)	
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78641-213-50	1200 mL in 1 BAG; Type 0: Not a Combination Product	03/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/16/2020	

Labeler - Global Equipment Company (001472216)**Registrant** - KutoI Products Company (004236139)**Establishment**

Name	Address	ID/FEI	Business Operations
KutoI Product Company		004236139	manufacture(78641-213)