

**RX200 FOAMING INSTANT HAND SANITIZER- benzalkonium chloride liquid**  
**The Bullen Companies, 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.*

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**RX200 Foaming Instant Hand Sanitizer**

**Uses**

Products 17 & 78: For handwashing to decrease bacteria on skin.

Product 41: Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

**Purpose**

Products 17 & 78: Antibacterial Agent

Product 41: Antibacterial Handwashing

**Active Ingredient**

Benzalkonium Chloride 0.13% w/w

**Warnings**

Products 17 & 41: **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 irritations develops. 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.

Product 78: **For external use only. Do not use in the eyes.** In rare instances of redness or irritation, discontinue use. 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.

**Inactive Ingredients**

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

**Directions**

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

**Warnings**

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

**AIRX 200**

**Foaming Instant Hand Sanitizer**  
with Aloe & Vitamin E

**Assainissant Instantané**  
**Moussant pour les Mains**

**Higienizador Instantáneo**  
**Espumoso para las Manos**

Contains No Alcohol

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Benzalkonium Chloride 0.13%	Antibacterial Handwashing
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.</li> </ul>	
<b>Warnings</b>	
<ul style="list-style-type: none"> <li>For external use only. Avoid contact with eyes. If contact occurs, flush with water.</li> <li>Stop use and ask a doctor if, in rare instances, redness or irritation develop. If condition persists for more than 72 hours, consult a physician.</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a poison control center.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>To decrease bacteria on skin, apply small amount to palm. Briskly rub, covering hands with product until dry.</li> </ul>	
<b>Inactive Ingredients</b> Water, Propylene Glycol, Cocamidopropyl Betaine, Aloe Barbadosis Leaf, Tocopheryl Acetate, PEG-7 Glyceryl Cocoate, Fragrance, Phenoxyethanol, Tetrasodium EDTA.	

LA373J-0712

**Ingrédient actif** Chlorure de benzalkonium 0,13% (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 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, appliquez une petite quantité sur la paume. Appliquez et faites pénétrer dans la peau en frottant.

**Ingrédients inactifs** Eau, parfum, feuille d'aloès barbadensis, acétate tocophérolique (vitamine E), bétaïne cocamidopropyle, propylène glycol, phénoxyéthanol, PEG-7 cocoate glycérylique, tétrasodium d'EDTA.

**Ingrédients Actives** Cloruro de benzalkonium 0,13% (Agent antibacterial) **Uso** 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** Para disminuir las bacterias en la piel, aplique una pequeña cantidad en la palma. Frota cubriendo las manos con firmeza hasta que el producto se seque. **Ingredientes Inactivos** Agua, perfume, hoja de aloe barbadensis, acetato tocoferilico (vitamina E), betaina cocamidopropilica, propilén glicol, fenoxietanol, PEG-7 cocoato glicérol, tetrasodio de EDTA.

Net Contents: 1000 mL (33.8 Fl. Oz.)      Manufactured for: AIRX Laboratories  
Folcroft, Pa 19032 • 610-534-8900

bag label

**KUTOL**

Products Company  
Skin Care Specialists

513-527-5500  
513-527-5506 fax  
blevenson@kutol.com

Label No. LA373J

Size 3 x 5 Unwind 1

Colors Black

Printed on \_\_\_\_\_

Formula 207 FG# 20741BCO

Revision: 7/21/10 change to formula 207 instead of 682, LA number changed 7/19/12 add Leaf to aloe b, take out hyphen in LA number



LA-14M  
1.7 oz. sample size

**KURTAL**  
 Products Company  
 One Day Operations  
 513-527-8900  
 513-527-8906 fax  
 info@kurtal.com

Label No. LA14M  
 Size 2.25 x 4 Unwind  
 Colors PMS 365 green, Process Cyan,  
239 magenta, Black  
 Printed on \_\_\_\_\_  
 Formula 207

Item #: 207179C2  
 12/27/10 - formula changed from 002 to 207  
 Revised: 1/22/12 - new graphics



LA378Z



LA378Y



LA378Z  
SIDE 2 UNDERNEATH

1/10/18  
this label has been changed to formula 207



Private Company  
Site Care Specialist  
513-527-5500  
513-527-5506 fax  
hansen@eutol.com

Label No. LA378Z  
 Size Unwind  
 Colors PM9 Process Blue, 365 green, 166 red  
black, Warm Gray 4  
 Printed on \_\_\_\_\_  
 Formula 207  
 1/10/18 change to formula 207 (previously 002)  
 1/10/18 change graphics



Private Company  
Site Care Specialist  
513-527-5500  
513-527-5506 fax  
hansen@eutol.com

Label No. LA378Y  
 Size Unwind  
 Colors PM9 Process Blue, 365 green, 166 red, black  
 Printed on \_\_\_\_\_  
 Formula 207  
 1/10/18 change to formula 207 (previously 002)  
 1/10/18 change graphics

## RX200 FOAMING INSTANT HAND SANITIZER

benzalkonium chloride liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57356-207
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	4.918 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	18.915 g in 100 mL
<b>WATER</b> (UNII: 059QF0K00R)	98.258 mL in 100 mL
<b>PEG-7 GLYCERYL COCOATE</b> (UNII: VNX7251543)	4.918 g in 100 mL
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	18.915 g in 100 mL
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	15.132 g in 100 mL
<b>MONOSODIUM ETHYLENEDIAMINETETRAACETATE</b> (UNII: KBO8XM1K0V)	1.51318 g in 100 mL
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.000083 g in 100 mL
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	0.000083 g in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57356-207-17	50 mL in 1 BOTTLE, PUMP		
2	NDC:57356-207-41	1000 mL in 1 POUCH		
3	NDC:57356-207-78	950 mL in 1 BOTTLE, PUMP		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/14/2009	

**Labeler** - The Bullen Companies, Inc. (002373462)**Registrant** - Kutol Products Company, Inc. (004236139)**Establishment**

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc		004236139	manufacture(57356-207) , analysis(57356-207) , pack(57356-207)