

## **ANTIBACTERIAL HAND CLEANSER- benzalkonium chloride soap Kimball Midwest**

*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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### **Kimball Midwest F215F**

#### **Dosage and Administration**

**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 Ingredient Section**

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

#### **Indications and Usage Section**

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

#### **Keep Out Of Reach Of Children Section**

**Keep Out Of Reach Of Children** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Purpose Section**

**Purpose** Antibacterial Handwashing

#### **Active Ingredient Section**

**Active Ingredient** Benzalkonium Chloride 0.13% w/w

#### **Warnings Section**

##### **Warnings**

**For external use only.**

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

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

Principal Display Label

**KIMBALL  
MIDWEST**

# KIM-STAT

**Antibacterial Hand Cleaner**

- PROVEN TO KILL A BROAD SPECTRUM OF GERMS & BACTERIA
- MILD YET EFFECTIVE • PLEASANT SPICY FLORAL FRAGRANCE

<p><b>Drug Facts</b></p> <p><b>Active Ingredient</b> Benzalkonium Chloride 0.13% w/w.....Antibacterial Handwashing</p> <p><b>Purpose</b> Antibacterial Handwashing</p> <p><b>Uses</b> ■ Handwash to help decrease bacteria on the skin.</p> <p><b>Warnings</b> 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.</p> <p>Net Contents: 3.785 L (one gallon)</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> ■ 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.</p> <p><b>Inactive Ingredients</b> Water, Cetrimonium Chloride, Lauramine Oxide, Sorbitol, Cocamide MEA, Sodium Chloride, PEG-120 Methyl Glucose Dioleate, Sodium Lauryl Sulfate, Citric Acid, Fragrance, Disodium EDTA, Methylisothiazolinone, Methylchloroisothiazolinone, Yellow 5, Red 33.</p> <p>80-1122      MG429EP Manufactured for: KIMBALL MIDWEST Columbus, OH / Dallas, TX / Reno, NV 1-800-233-1294 MADE IN USA</p>
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**KIMBALL  
MIDWEST**

# KIM-STAT

**Antibacterial  
Hand Cleaner**

PROVEN TO KILL A BROAD SPECTRUM OF  
GERMS & BACTERIA

- 
- MILD YET EFFECTIVE
- 

PLEASANT SPICY FLORAL FRAGRANCE

80-1122  
Net Contents: 3.785 L (one gallon)

5009KIM

<p>DO NOT PRINT THIS BOX</p> <p>KUTOL INTERNAL</p> <p>Approved _____</p> <p>Date _____</p> <p>Changes: _____</p>	<p>DO NOT PRINT THIS BOX</p> <p>Label No: MG429EP</p> <p>Color: Black</p> <p>Formula #: 215F    Item #: 5009KIM</p> <p><small>Revised: 7/18/13 - Change formula from 050 to 050F; change label no. to MG429KIG from MG429KIG, add "MADE IN USA"; 4/27/17 - change to formula 215F from 050F (no triclosan), assign new no. (KIG MG429KIG)</small></p> <p style="text-align: center;">DO NOT PRINT THIS BOX</p>
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<b>ANTIBACTERIAL HAND CLEANSER</b>			
benzalkonium chloride soap			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66608-215
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.013 mg in 1 mL
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>		<b>Strength</b>	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)			
COCOYL METHYL MONOETHANOLAMINE (UNII: 79G1T427CF)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
ACID RED 35 (UNII: 02BXM5Q7GE)			
WATER (UNII: 059QF0KO0R)			
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)			
SORBITOL (UNII: 506T60A25R)			

**PEG-120 METHYL GLUCOSE DIOLEATE** (UNII: YM0K64F20V)

**CITRIC ACID ACETATE** (UNII: DSO12WL7AU)

**SODIUM CHLORIDE** (UNII: 451W47IQ8X)

**LAURAMINE OXIDE** (UNII: 4F6FC4MI8W)

**DISODIUM EDTA-COPPER** (UNII: 6V475AX06U)

**SODIUM LAURIMINODIPROPIONATE** (UNII: 7G447D0DH9)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66608-215-78	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2017	
2	NDC:66608-215-65	800 mL in 1 BAG; Type 0: Not a Combination Product	06/28/2017	
3	NDC:66608-215-09	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/28/2017	

**Labeler** - Kimball Midwest (017906231)

**Registrant** - Kutol Products, Inc. (004236139)

### Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products, Inc.		004236139	manufacture(66608-215)

Revised: 8/2023

Kimball Midwest