

## **MADA MEDICAL FOAM SANITIZER- benzethonium chloride liquid**

### **Mada Medical**

*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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### **Drug Facts**

Benzethonium chloride 0.2 %

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

If swallowed, get medical help or contact a poison control center.

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

For external use only. Avoid contact with eyes. If contact occurs, flush with water.

To decrease bacteria on skin, apply small amount to palm. Briskly rub, covering hands with product until dry. Children should be supervised when using product.

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

Foaming Instant Hand Sanitizer Bag Label

# MADAFOAM BOTTLE LABEL (1.7 FL.OZ. SIZE)

Prints 2-color Pantone Blue 275C and Yellow on White Poly-Propylene with Laminate.

<p><b>MadaFoamPlus</b></p> <p><b>Foaming Instant Hand Sanitizer</b></p> <p>with <b>Aloe and Vitamin E</b></p> <p><i>USE WITHOUT WATER</i></p> <p><b>REORDER NO. 7014</b></p> <p>NET CONTENTS 50 ml. (1.7 Fl. Oz.)</p>	<p><b>Drug Facts</b></p> <table><tr><td><b>Active Ingredient</b></td><td><b>Purpose</b></td></tr><tr><td>Benzethonium Chloride 0.2% . . . . .</td><td>Antibacterial Agent</td></tr></table>	<b>Active Ingredient</b>	<b>Purpose</b>	Benzethonium Chloride 0.2% . . . . .	Antibacterial Agent
	<b>Active Ingredient</b>	<b>Purpose</b>			
	Benzethonium Chloride 0.2% . . . . .	Antibacterial Agent			
	<p><b>Uses</b> ■ For handwashing to decrease bacteria on skin.</p>				
<p><b>Warnings</b> ■ <b>For external use only.</b> ■ <b>Avoid contact with eyes.</b> if contact occurs, flush with water. ■ <b>Stop use and ask a doctor if,</b> in rare instances, redness or irritation develops and persists for over 72 hours. ■ <b>Keep out of reach of children.</b> If swallowed, contact a physician or poison control center.</p>					
<p><b>Directions</b></p> <p>■ To decrease bacteria on skin, apply a small amount to palm. Briskly rub, covering hands with product until dry.</p>					
<p><b>Inactive Ingredients</b></p> <p>Water, Fragrance, Aloe Barbadensis, Tocopheryl Acetate (Vitamin E), Cocamidopropyl Betaine, Propylene Glycol, Phenoxyethanol, PEG-7 Glyceryl Cocoate, Tetrasodium EDTA.</p>					
<p>Manufactured For:  <b>MADA, INC.</b> LA18F-0311</p> <p>625 Washington Avenue Carlstadt, NJ 07072 800-526-6370</p>					

benzethonium chloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11928-682
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Benzethonium Chloride</b> (UNII: PH41D05744) (Benzethonium - UNII:1VU15B70BP)	Benzethonium Chloride	0.2 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>Water</b> (UNII: 059QF0K00R)	
<b>Cocamidopropyl Betaine</b> (UNII: 5OCF3011KX)	
<b>Edetate Sodium</b> (UNII: MP1J8420LU)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Aloe Vera Flower</b> (UNII: 575DY8C1ER)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>Glyceryl Cocoate</b> (UNII: WVK1CT5994)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:11928-682-41	1000 mL in 1 BAG		
2	NDC:11928-682-17	50 mL in 1 BOTTLE, PUMP		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	01/02/2010	

**Labeler** - Mada Medical (048411862)

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

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Kutol Products Company, Inc.		004236139	manufacture