# GEA COSMETICS LABS HAND AND BODY SANITIZER- benzalkonium chloride 0.13% spray

### Romano Group, LLC

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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### **GEA Cosmetics Labs Hand & Body Sanitizer**

### **Active Ingredient**

Benzalkonium Chloride 0.13%

### **Purpose**

Antiseptic

### Uses

Hand Sanitizer to to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### Warnings

For External Use only.

### Do Not Use

On children less that 2 months of age on open skin wounds

### When using this product

keep out of eyes, ears, and mouth, in case of contact with eyes, rinse eyes thoroughly with water

### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

### Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

### **Other Information**

Store between 15-30C (59-86F) Avoid Freezing and excessive heat above 40C (104F)

### **Inactive Ingredients**

### **GEA Cosmetics Labs Hand & Body Sanitizer**







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## GEA COSMETICS LABS HAND AND BODY SANITIZER

benzalkonium chloride 0.13% spray

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:81237-001

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	0.61 g in 472 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
UREA (UNII: 8W8T17847W)	

	Packaging				
:	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
	NDC:81237-001-16	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 21		
	NDC:81237-001-10	$3785\ mL$ in $1\ BOTTLE;$ Type 0: Not a Combination Product	0 1/0 1/20 21		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	0 1/0 1/20 21		

# Labeler - Romano Group, LLC (037493262)

Revised: 1/2021 Romano Group, LLC