

**BODY PRESCRIPTIONS COCONUT INFUSED WITH VITAMIN E ANTIBACTERIAL  
FOAMING HAND- benzalkonium chloride soap  
ENCHANTE ACCESSORIES 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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**50563-411/JAS21FCO**

**Active Ingredient**

Benzalkonium Chloride 0.13%

**Purpose**

Antibacterial

**Use**

- For hand washing to decrease bacteria on the skin

**WARNINGS**

For external use only

When using this product, keep out of eyes. In case of contact with eyes, flush thoroughly with water.

Stop use and ask a doctor if skin irritation develops.

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Apply a small amount to hands, lather for seconds, then rinse with warm water.

**Inactive ingredients**

Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Red 4, Yellow 5

224\*55mm

<p><b>BODY PRESCRIPTIONS</b></p> <p>ANTI-BACTERIAL</p> <p><b>FOAMING HAND SOAP</b></p> <p><i>Coconut</i></p> <p>INFUSED WITH VITAMIN E</p> <p>kills bacteria soften • hydrates • protects • cleanses</p> <p><b>8.6 fl oz (254ml)</b></p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <td><b>Active ingredient</b> Benzalkonium Chloride(0.13%)</td> <td><b>Purpose</b> Antibacterial</td> </tr> <tr> <td colspan="2"><b>Uses</b> For hand washing to decrease bacteria on the skin</td> </tr> <tr> <td colspan="2"><b>Warning</b> For external use only. When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water. Stop use and see a doctor if skin irritation develops. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.</td> </tr> <tr> <td colspan="2"><b>Directions</b> • Apply a small amount to hands, lather for 20 seconds, then rinse with warm water.</td> </tr> <tr> <td colspan="2"><b>Other information</b> • Do not store above 105°F    • May discolor some fabrics    • Harmful to wood finishes and plastics</td> </tr> <tr> <td colspan="2"><b>Inactive ingredients</b> Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Red 4, Yellow 5</td> </tr> </table> <p><b>8.6 FL OZ (254 ML)</b></p> <p><small>NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA DISTRIBUTED BY ENCHANTÉ ACCESSORIES INC., NEW YORK, NY 10016</small></p> <p><small>LOT NO.: BL011621-2 MFG. 01/16/2021 EXP. 01/16/2023</small></p>	<b>Active ingredient</b> Benzalkonium Chloride(0.13%)	<b>Purpose</b> Antibacterial	<b>Uses</b> For hand washing to decrease bacteria on the skin		<b>Warning</b> For external use only. When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water. Stop use and see a doctor if skin irritation develops. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.		<b>Directions</b> • Apply a small amount to hands, lather for 20 seconds, then rinse with warm water.		<b>Other information</b> • Do not store above 105°F    • May discolor some fabrics    • Harmful to wood finishes and plastics		<b>Inactive ingredients</b> Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Red 4, Yellow 5	
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## BODY PRESCRIPTIONS COCONUT INFUSED WITH VITAMIN E ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50563-411
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CO CAMIDO PROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>DISODIUM HEDTA</b> (UNII: KME849MC7A)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-411-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/18/2021	

**Labeler** - ENCHANTE ACCESSORIES INC. (186050696)

## Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-411)

Revised: 1/2021

ENCHANTE ACCESSORIES INC.