

**BODY PRESCRIPTIONS WINTER GARDENIA 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.*

-----  
**50563-267/JAS21F07**

**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**

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.

**Other Information**

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

**Inactive ingredients**

Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Yellow 5, Red 4, Blue 1

white

224\*50mm

<p><b>BODY PRESCRIPTIONS</b></p> <p>ANTI-BACTERIAL <b>FOAMING HAND SOAP</b></p> <p><i>Winter Gardenia</i> INFUSED WITH VITAMIN E</p> <p>kills bacteria soften · hydrate · protect · cleanse 8.6 FL oz (254 mL)</p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Benzalkonium Chloride (0.13%)</td> <td>Antibacterial</td> </tr> </table> <p><b>Uses</b> For hand washing to decrease bacteria on the skin</p> <p><b>Warnings:</b></p> <ul style="list-style-type: none"> <li>For external use only.</li> <li>When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water.</li> <li>Stop use and ask a doctor if irritation develops.</li> <li>Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.</li> </ul> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Apply a small amount to hands, lather for 20 seconds, then rinse with warm water.</li> </ul> <table border="1"> <tr> <th>Other information</th> <th>Inactive ingredients</th> </tr> <tr> <td> <ul style="list-style-type: none"> <li>Do not store above 120°F</li> <li>May discolor some fabrics</li> <li>Harmful to wood finishes and plastics</li> </ul> </td> <td>           Water, Cocamidopropyl Betaine, DiClM Hydantoin, Fragrance, Sodium Sulfate, Citric Acid, Tocopheryl Acetate, Yellow 5, Red 4, Blue 1         </td> </tr> </table> <p>NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA FORMULATED EXCLUSIVELY AND DISTRIBUTED BY: ENCHANTANTE ACCESSORIES INC., NEW YORK, NY 10016 NDC: 50563-267 LOT NO.: BL091320-2 MFG: 09/13/2020 EXP: 09/12/2022</p> 	Active ingredient	Purpose	Benzalkonium Chloride (0.13%)	Antibacterial	Other information	Inactive ingredients	<ul style="list-style-type: none"> <li>Do not store above 120°F</li> <li>May discolor some fabrics</li> <li>Harmful to wood finishes and plastics</li> </ul>	Water, Cocamidopropyl Betaine, DiClM Hydantoin, Fragrance, Sodium Sulfate, Citric Acid, Tocopheryl Acetate, Yellow 5, Red 4, Blue 1
Active ingredient	Purpose								
Benzalkonium Chloride (0.13%)	Antibacterial								
Other information	Inactive ingredients								
<ul style="list-style-type: none"> <li>Do not store above 120°F</li> <li>May discolor some fabrics</li> <li>Harmful to wood finishes and plastics</li> </ul>	Water, Cocamidopropyl Betaine, DiClM Hydantoin, Fragrance, Sodium Sulfate, Citric Acid, Tocopheryl Acetate, Yellow 5, Red 4, Blue 1								

## BODY PRESCRIPTIONS WINTER GARDENIA 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:50563-267
<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: 5OCF3011KX)	
<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: 059QF0K00R)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-267-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/23/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-267)

Revised: 9/2020

ENCHANTE ACCESSORIES INC.