

**BODY PRESCRIPTIONS WINTER GARDENIA INFUSED WITH VITAMIN E  
ANTIBACTERIAL HAND- benzalkonium chloride lotion  
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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**50563-337/JAS21F18**

**Active Ingredient**

Benzalkonium Chloride 0.13%

**Purpose**

Antibacterial

**Use**

- To help reduce the 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 accident ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Apply a small amount to palms and rub hands together thoroughly

**Other Information**

Do not store above 105F

May discolor some fabrics

Harmful to wood finishes and plastics

**Inactive ingredients**

Water, Cetearyl Alcohol, Mineral Oil, Glyceryl Stearate, PEG 100 Stearate, Glycerin, C13-14 Isoparaffin, Laureth-7, Polyacrylamide, Phenoxyethanol, Benzyl Alcohol, Fragrance (Parfum), Butyrospermum Parkii (Shea) Butter, Citric Acid, Tocopheryl Acetate, Yellow 5, Red 4, Blue

189\*70mm

**BODY PRESCRIPTIONS**

ANTI-BACTERIAL  
**HAND LOTION**

*Winter Gardenia*  
INFUSED WITH VITAMIN E


kills bacteria  
soften - hydrates - protects - moisturizing

8 fl oz (236.6ml)

**Drug Facts**

<b>Active ingredient</b> Benzalkonium Chloride(0.13%)	<b>Purpose</b> Antibacterial
<b>Uses</b> - To help reduce the bacteria on the skin	
<b>Warnings:</b>	
• <b>For external use only.</b>	
• <b>When using this product</b> keep out of eyes. In case of contact with eyes, flush thoroughly with water.	
• <b>Stop use and ask a doctor</b> if skin irritation develops.	
• <b>Keep out of reach of children.</b> In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.	
<b>Directions</b>	
• Apply a small amount to palm and rub hands together thoroughly.	
<b>Other information</b>	<b>Inactive ingredients</b>
• Do not store above 105°F	Water, Cetearyl Alcohol, Mineral Oil, Glycerin Stearate, Glycerin, PEG-100 Stearate, C13-14 Isoparaffin, Polyacrylamide, Laureth-7, Phenoxyethanol, Benzyl Alcohol, Benzoic Acid, Fragrance, Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Yellow 5, Red 4, Blue 1.
• May discolor some fabrics	
• Harmful to wood finishes and plastics	

NOT TESTED ON ANIMALS. FOR ADULT USE ONLY.  
DESIGNED IN THE USA / MADE IN CHINA  
FORMULATED EXCLUSIVELY AND DISTRIBUTED BY:  
ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016  
8 FL OZ (236.6 ML)  
LOT NO.: BL091120-2  
MFG: 09/11/2020 EXP: 09/10/2022



## BODY PRESCRIPTIONS WINTER GARDENIA INFUSED WITH VITAMIN E ANTIBACTERIAL HAND

benzalkonium chloride lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50563-337
<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
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-337-01	236.6 mL in 1 BOTTLE; Type 0; Not a Combination Product	10/11/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/11/2020	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-337)

Revised: 10/2020

ENCHANTE ACCESSORIES INC.