

**BODY PRESCRIPTIONS SUGAR COOKIE 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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**50563-458/JAS21X11**

**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 accident ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Apply a small amount to hands, lather for 20 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, Red 4, Yellow 5, Blue 1

FILL COLOR =  
PANTONE 7514 C @ 30%

10375~10377-2 (JAS21X11)

224\*55mm



<b>BODY PRESCRIPTIONS</b>																									
<b>ANTI-BACTERIAL FOAMING HAND SOAP</b>																									
<i>Sugar Cookie</i>																									
INFUSED WITH VITAMIN E																									
soften · hydrate · protect · cleanse																									
<i>8.6 fl oz (254ml)</i>																									
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## BODY PRESCRIPTIONS SUGAR COOKIE 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:50563-458
<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>COCAMIDOPROPYL 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: 059QF0KO0R)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-458-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2021	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/02/2021	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-458)

Revised: 7/2021

ENCHANTE ACCESSORIES INC.