

**BODY PRESCRIPTIONS PEPPERMINT 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.

50563-457/JAS21X10

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 accidenta ingestion, seek professional assistance or contact a Poison Control Center immdiately.

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 33, Yellow 5

FILL COLOR =
PANTONE 587 C @ 30%

10375~10377-1 (JAS21X10)

224*55mm



BODY PRESCRIPTIONS

**ANTI-BACTERIAL
FOAMING
HAND SOAP**

Peppermint

INFUSED WITH VITAMIN E
soften · hydrate · protect · cleanse

8.6 fl oz (254ml)

Drug Facts

Active ingredient	Purpose
Benzalkonium Chloride (0.13%)	Antibacterial
Uses For hand washing to decrease bacteria on the skin	
Warning 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 20 seconds, then rinse with warm water.	
Other information	
• Do not store above 102°F • 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 33, Yellow 5	
8.6 FL OZ (254 ML)	

BODY PRESCRIPTIONS PEPPERMINT INFUSED WITH VITAMIN E ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-457
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
DISODIUM HEDTA (UNII: KME849MC7A)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:50563-457-01	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(50563-457)

Revised: 7/2021

ENCHANTE ACCESSORIES INC.