

**BODY PRESCRIPTIONS WINTERBERRY 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.

50563-460/JAS21X13

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, Blue 1, Red 33

FILL COLOR =
PANTONE 658 C @ 30%

10375~10377-4 (JAS21X13)

224*55mm



BODY PRESCRIPTIONS		ANTI-BACTERIAL FOAMING HAND SOAP																																	
<i>Winterberry</i>		INFUSED WITH VITAMIN E																																	
soften · hydrate · protect · cleanse																																			
<i>8.6 fl oz (254ml)</i>																																			
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BODY PRESCRIPTIONS WINTERBERRY INFUSED WITH VITAMIN E ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-460
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:50563-460-01	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(50563-460)

Revised: 7/2021

ENCHANTE ACCESSORIES INC.