

**BODY PRESCRIPTIONS INFUSED WITH VITAMIN E WINTERBERRY
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.

50563-468/JAS21XL4

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

Directions

Apply a small amount to palm and rub hands together thoroughly

Other Information

Do not store above 105F

May doscolor some fabrics

Harmful to wood finishes and plastics

Inactive ingredients

Water, Cetearyl Alcohol, Mineral Oil, Glyceryl Stearate, Glycerin, PEG-100 Stearate, C13-

14 Isoparaffin, Polyacrylamide, Laureth-7, Phenoxyethanol, Benzyl Alcohol, Benzoic Acid, Fragrance (Parfum), Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Blue 1, Red 33

10375~10377-8 (JAS21XL4)

FILL COLOR =
PANTONE 658 C @ 30%

189*70mm



BODY PRESCRIPTIONS	
ANTI-BACTERIAL	
HAND LOTION	
<i>Winterberry</i>	
INFUSED WITH VITAMIN E	
soften · hydrates · protects · moisturizing	
<i>8 fl oz (236.6 ml)</i>	
Drug Facts	
Active ingredient Benzalkonium Chloride(0.13%)	Purpose Antibacterial
Uses To help reduce the 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 palm and rub hands together thoroughly.	
Other information Do not store above 105°F May discolor some fabrics Harmful to wood finishes and plastics	
Inactive ingredients Water, Cetearyl Alcohol, Mineral Oil, Glyceryl 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, Blue 1, Red 33.	
NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA DISTRIBUTED BY ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016	
8 FL OZ (236.6 ML)	
LOT NO.: BL071921-4 MFG: 07/19/2021 EXP: 07/18/2023	

BODY PRESCRIPTIONS INFUSED WITH VITAMIN E WINTERBERRY ANTIBACTERIAL HAND

benzalkonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-468
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
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWW)	
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-468-01	236.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/04/2021	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-468)

Revised: 7/2021

ENCHANTE ACCESSORIES INC.