

**BODY PRESCRIPTIONS FRENCH LAVENDER 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.

50563-331/JAS21F12

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 palms 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, PEG 100 Stearate, Glycerin, C13-14 Isoparaffin, Laureth-7, Polyacrylamide, Phenoxyethanol, Benyl Alcohol, Fragrance (Parfum), Butyrospermum Parkii (Shea) Butter, Citric Acid, Tocopheryl Acetate, Red 33, Blue 1

BODY PRESCRIPTIONS

ANTI-BACTERIAL

HAND LOTION

French Lavender

INFUSED WITH VITAMIN E

kills bacteria
soften - hydrates - protects - moisturizing

8 fl oz (236.6 mL)

Drug Facts

Active ingredient Benzalkonium Chloride(0.13%)	Purpose Antibacterial
Uses - To help reduce the bacteria on the skin	
Warnings: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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, Glycenn, PEG-100 Stearate, C13-14 Isoparaffin, Polyacrylamide, Laureth-7, Phenoxyethanol, Benzyl Alcohol, Benzoic Acid, Fragrance, Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Red 33, Blue 1.

NOT TESTED ON ANIMALS. FOR ADULT USE ONLY.
 DESIGNED IN THE USA / MADE IN CHINA
 FORMULATED EXCLUSIVELY AND DISTRIBUTED BY:
 ENCHANTÉ ACCESSORIES INC., NEW YORK, NY 10016
 8 FL OZ (236.6 ML)
 LOT NO.: BL091020-1
 MFG: 09/10/2020 EXP: 09/09/2022

BODY PRESCRIPTIONS FRENCH LAVENDER INFUSED WITH VITAMIN E ANTIBACTERIAL HAND

benzalkonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-331
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: 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)		
	D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
	FD&C BLUE NO. 1 (UNII: HBR47K3TBD)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-331-01	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(50563-331)

Revised: 10/2020

ENCHANTE ACCESSORIES INC.