BODY PRESCRIPTIONS FRESH CRISP AIR 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.

50563-338/JAS21F19

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, Benzyl Alcohol, Fragrance (Parfum), Butyrospermum Parkii (Shea) Butter, Citric Acid, Tocopheryl Acetate, Blue 1

189*70mm

BODY PRESCRIPTIONS ANTI-BACTERIAL HAND LOTION Fresh Crisp Air soften · hydrates · protects · moisturizing 8 fl oz (236.6ml)

Drug Facts			
Active ingredient Benzalkonium Chloride(0.13%)	Purpose Antibacterial		
Uses . To help reduce the bacter	ia 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, - \$top use and ask a doctor if skin initiation 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 Inactive ingredients			
Do not store above 105°F May discolor some fabrics Harmful to wood finishes and plastics	Water, Cetearyl Alcohol, Mineral Oil, Glyceryl Stearate, Glycerin, PEC-100 Stearate, C13-14 Isoparan PEC-100 Stearate, C13-14 Isoparan Penerover, Penoxyethanol, Benzyl Alcohol, Benzoic Acid, Fragrance, Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Blue 1,		

NOTTESTED ON ANIMALS. FOR ADULT USE ONLY.
DESIGNED IN THE USA, WADE IN CHINA
FORMULATE DESCRIBENCY. MADE IN CHINA
FORMULATE DESCRIBENCY. NEW YORK, NY 10016
8FL OZ (236.6 ML)
LOT NO.: BLO91120-3
MFG: 09/11/2020 EXP: 09/10/2022



BODY PRESCRIPTIONS FRESH CRISP AIR INFUSED WITH VITAMIN E ANTIBACTERIAL HAND

benzalkonium chloride lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-338	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	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: PDC6 A3C0 OX)	
WATER (UNII: 059QF0KO0R)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
BUTYRO SPERMUM PARKII (SHEA) BUTTER UNSAPO NIFIABLES (UNII: 0 C9 AC7 D6 XU)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

ı	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:50563-338- 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(50563-338)	

Revised: 10/2020 ENCHANTE ACCESSORIES INC.