

**BODY PRESCRIPTIONS BUTTER PECAN 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.

50563-428/JAS21FL4

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 accident 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 105F

May discolor some fabrics

Harmful to wood finishes and plastics

Inactive ingredients

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

Stearate, Phenoxyethanol, Polyacrylamide, Benzyl Alcohol, Fragrance (Parfum), C13-14 Isoparaffin, Laureth-7, Benzoic Acid, Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Red 4, Yellow 5

10345-3-7-11 (JAS21FL4)

189*70mm

<p>BODY PRESCRIPTIONS</p> <p>ANTI-BACTERIAL</p> <p>HAND LOTION</p> <p><i>Butter Pecan</i></p> <p>INFUSED WITH VITAMIN E</p> <p>kills bacteria</p> <p><small>soften · hydrate · protect · moisturizing</small></p> <p><i>8 fl oz (236.6 ml)</i></p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient Benzalkonium Chloride(0.13%)</td> <td>Purpose Antibacterial</td> </tr> <tr> <td colspan="2">Uses To help reduce the bacteria on the skin</td> </tr> <tr> <td colspan="2">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.</td> </tr> <tr> <td colspan="2">Directions Apply a small amount to palm and rub hands together thoroughly.</td> </tr> <tr> <td colspan="2">Other information Do not store above 105°F May discolor some fabrics Harmful to wood finishes and plastics</td> </tr> <tr> <td colspan="2">Inactive ingredients Water (Aqua), Cetearyl Alcohol, Mineral Oil, Glyceryl Stearate, Glycerin, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Benzyl Alcohol, Fragrance (Parfum), C13-14 Isoparaffin, Laureth-7, Benzoic Acid, Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Red 4, Yellow 5.</td> </tr> </table> <p>NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA DISTRIBUTED BY ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016</p> <p>8 FL OZ (236.6 ML)</p> <p>LOT NO.: BL040221-3 MFG: 04/02/2021 EXP: 04/01/2023</p> 	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 (Aqua), Cetearyl Alcohol, Mineral Oil, Glyceryl Stearate, Glycerin, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Benzyl Alcohol, Fragrance (Parfum), C13-14 Isoparaffin, Laureth-7, Benzoic Acid, Citric Acid, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Red 4, Yellow 5.	
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BODY PRESCRIPTIONS BUTTER PECAN INFUSED WITH VITAMIN E ANTIBACTERIAL HAND

benzalkonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-428
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)

FD&C RED NO. 4 (UNII: X3W0AM1JLX)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-428-01	236.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/27/2021	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-428)

Revised: 3/2021

ENCHANTE ACCESSORIES INC.