

**BODY PRESCRIPTIONS FRENCH LAVENDER 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.

50563-261/JAS21F01

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

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 seconds, then rinse with warm water.

Inactive ingredients

Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Red 33, Blue 1

10275-10296-10297-1 (JAS21F01)



white

224*50mm

<p>BODY PRESCRIPTIONS</p> <p>ANTI-BACTERIAL FOAMING HAND SOAP</p> <p><i>French Lavender</i></p> <p>INFUSED WITH VITAMIN E</p> <p>kills bacteria soften-hydrate-protect-cleanse</p> <p>8.6 fl oz (254ml)</p>	<table border="1"><tr><td>Drug Facts</td><td></td></tr><tr><td>Active ingredient Benzalkonium Chloride (0.13%)</td><td>Purpose Antibacterial</td></tr><tr><td colspan="2">Uses: For hand washing to decrease bacteria on the skin</td></tr><tr><td colspan="2">Warnings:</td></tr><tr><td colspan="2">• For external use only.</td></tr><tr><td colspan="2">• When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water.</td></tr><tr><td colspan="2">• Stop use and ask a doctor if skin irritation develops.</td></tr><tr><td colspan="2">• 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</td></tr><tr><td colspan="2">• Apply a small amount to hands, lather for 20 seconds, then rinse with warm water.</td></tr><tr><td>Other information</td><td>Inactive ingredients</td></tr><tr><td>• Do not store above 100°F</td><td>Water, Cocamidopropyl Betaine, DMDM Hydantoin,</td></tr><tr><td>• May discolor some fabrics</td><td>Fragrance, Disodium EDTA, Citric Acid,</td></tr><tr><td>• Harmful to wood, linens and plastics</td><td>Tocopheryl Acetate, Red 33, Blue 1.</td></tr><tr><td colspan="2"><small>NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DISINFECTANT IN THE USA/MADE IN CHINA FORMULATED EXCLUSIVELY AND DISTRIBUTED BY: ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016 86 FL OZ (254 ML) LOT NO.: 18J991220 EXP: 09/11/2022 MFG: 09/10/2020</small></td></tr></table>	Drug Facts		Active ingredient Benzalkonium Chloride (0.13%)	Purpose Antibacterial	Uses: 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 accidental 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	Inactive ingredients	• Do not store above 100°F	Water, Cocamidopropyl Betaine, DMDM Hydantoin,	• May discolor some fabrics	Fragrance, Disodium EDTA, Citric Acid,	• Harmful to wood, linens and plastics	Tocopheryl Acetate, Red 33, Blue 1.	<small>NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DISINFECTANT IN THE USA/MADE IN CHINA FORMULATED EXCLUSIVELY AND DISTRIBUTED BY: ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016 86 FL OZ (254 ML) LOT NO.: 18J991220 EXP: 09/11/2022 MFG: 09/10/2020</small>	
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benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-261
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: 5OCF3O11KX)	
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 Date	Marketing End Date
1	NDC:50563-261-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/23/2020	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-261)