

BODY PRESCRIPTIONS GRAPEFRUIT 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.

50563-412/JAS21FGF

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. In case of accidental 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 4

10332-10333-10334-3 (JAS21FGF)

224*55mm

<p>BODY PRESCRIPTIONS</p> <p>ANTI-BACTERIAL</p> <p>FOAMING HAND SOAP</p> <p><i>Grapefruit</i></p> <p>INFUSED WITH VITAMIN E</p> <p>kills bacteria <small>soften hydrates protects cleanses</small></p> <p>8.6 fl oz (254ml)</p>	<table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active ingredient</td><td>Purpose</td></tr><tr><td>Benzalkonium Chloride(0.13%)</td><td>Antibacterial</td></tr><tr><td colspan="2">Uses For hand washing to decrease bacteria on the skin</td></tr><tr><td colspan="2">Warning 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 colspan="2">Other information</td></tr><tr><td colspan="2">• Do not store above 105°F • May discolor some fabrics • Harmful to wood finishes and plastics</td></tr><tr><td colspan="2">Inactive ingredients</td></tr><tr><td colspan="2">Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Red 4</td></tr><tr><td colspan="2"><small>NOT FOR USE ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA</small></td></tr><tr><td colspan="2"><small>DISTRIBUTED BY ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016</small></td></tr><tr><td colspan="2">8.6 FL OZ (254 ML)</td></tr></table>	Drug Facts		Active ingredient	Purpose	Benzalkonium Chloride(0.13%)	Antibacterial	Uses For hand washing to decrease 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 hands, lather for 20 seconds, then rinse with warm water.		Other information		• Do not store above 105°F • May discolor some fabrics • Harmful to wood finishes and plastics		Inactive ingredients		Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Red 4		<small>NOT FOR USE ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA</small>		<small>DISTRIBUTED BY ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016</small>		8.6 FL OZ (254 ML)	
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benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50563-412
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)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50563-412-01	254 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/18/2021	

Labeler - ENCHANTE ACCESSORIES INC. (186050696)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Afgamarine Biotechnology Co., Ltd.		420485152	manufacture(50563-412)

Revised: 1/2021

ENCHANTE ACCESSORIES INC.