

BODY PRESCRIPTIONS EUCALYPTUS 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.

50563-264/JAS21F04

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 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, Blue 1, Yellow 5

10275-10296-10297-4 (JAS21F04)



white

224*50mm

| | | | | | | | | | | | |
|---|---|---|---------------------------------|---|--|---|--|---|--|--|---|
| <p>BODY PRESCRIPTIONS</p> <p>ANTI-BACTERIAL FOAMING HAND SOAP</p> <p><i>Eucalyptus</i></p> <p>INFUSED WITH VITAMIN E</p> <p>kills bacteria soften • hydrate • protect • cleanse</p> <p>8.6 fl oz (254ml)</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 For hand washing to decrease bacteria on the skin</td></tr><tr><td colspan="2">Warnings<ul style="list-style-type: none">For external use onlyWhen 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.</td></tr><tr><td colspan="2">Directions Apply a small amount to hands, lather for 20 seconds, then rinse with warm water.</td></tr><tr><td>Other information<ul style="list-style-type: none">Do not store above 105°FMay discolor some fabricsAvoid skin, eyes, nose and mouth</td><td>Inactive ingredients Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Blue 1, Yellow 5</td></tr></table> <p><small>NOT TESTED ON ANIMALS. FOR ADULT USE ONLY. DESIGNED IN THE USA / MADE IN CHINA FORMULATED, PACKAGED AND DISTRIBUTED BY: ENCHANTE ACCESSORIES INC., NEW YORK, NY 10016</small></p> <p><small>861/1 021296-10297-4 LOT NO. - 18L091220-4 MFG-09/12/2020 EXP-09/11/2022</small></p> | Active ingredient Benzalkonium Chloride (0.13%) | Purpose Antibacterial | Uses For hand washing to decrease bacteria on the skin | | Warnings <ul style="list-style-type: none">For external use onlyWhen 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. | | Directions Apply a small amount to hands, lather for 20 seconds, then rinse with warm water. | | Other information <ul style="list-style-type: none">Do not store above 105°FMay discolor some fabricsAvoid skin, eyes, nose and mouth | Inactive ingredients Water, Cocamidopropyl Betaine, DMDM Hydantoin, Fragrance, Disodium EDTA, Citric Acid, Tocopheryl Acetate, Blue 1, Yellow 5 |
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BODY PRESCRIPTIONS EUCALYPTUS INFUSED WITH VITAMIN E ANTIBACTERIAL FOAMING HAND

benzalkonium chloride soap

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50563-264 |
| 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 BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50563-264-01 | 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(50563-264) |