

**HOME FORMATION ANTIBACTERIAL COCONUT- benzalkonium chloride liquid
PATCOS COSMETICS (INDIA) PRIVATE LIMITED**

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.

Active ingredient

Benzalkonium Chloride (0.13%)

Purpose

Antibacterial

Warnings

For external use only.

When using this product avoid contact with eyes. In case of eyes contact, flush with water.

Stop use and ask a doctor if irritation and redness develops.

Keep out of reach of children if swallowed, get medical help or contact a Poison control center right away.

Uses

For hand washing to decrease bacteria on the skin.

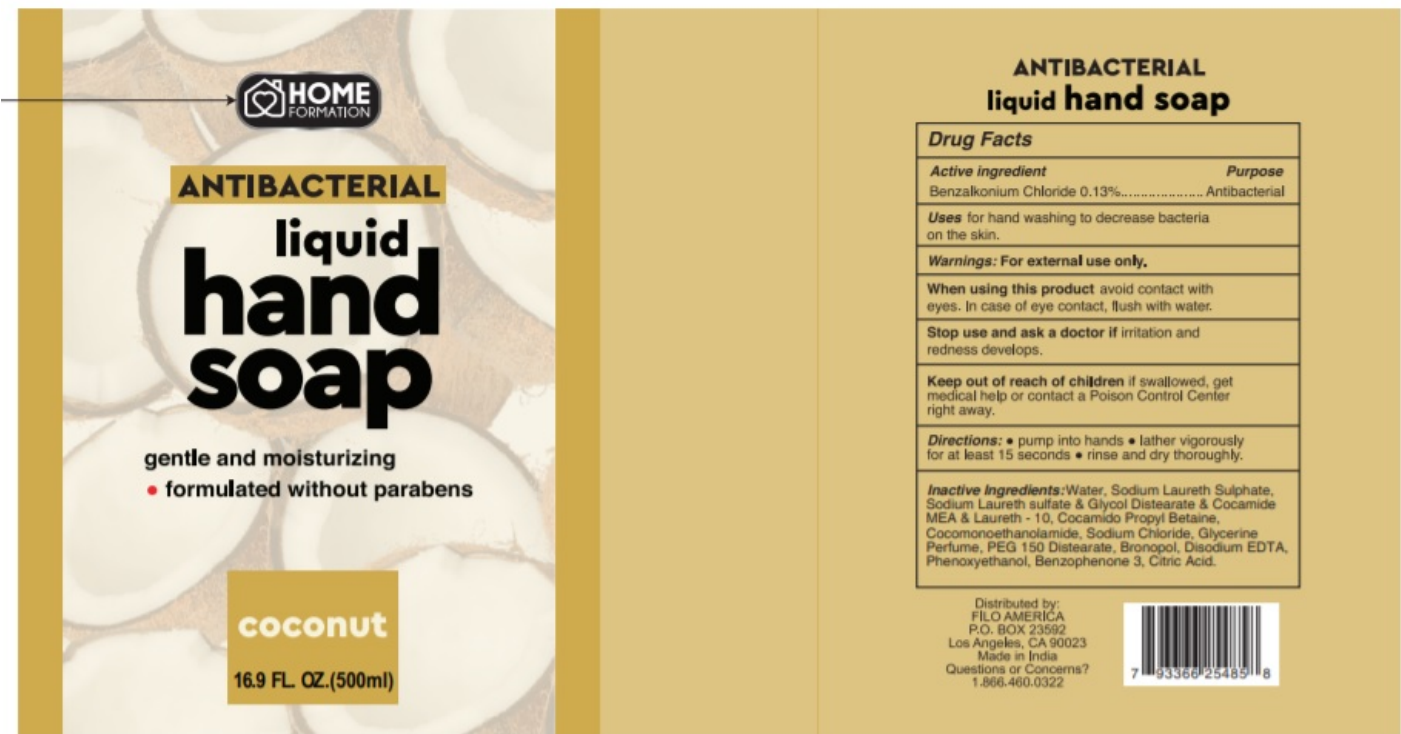
Directions

- Pump into hands.
- Lather vigorously for at least 15 seconds.
- Rinse and dry thoroughly.

Inactive ingredient

Water, Sodium Laureth Sulphate, Sodium Laureth sulfate & Glycol Distearate & Cocamide MEA & Laureth - 10, Cocamido Propyl Betaine, Cocomonoethanolamide, Sodium Chloride, Glycerine, Perfume, PEG 150 Distearate, Bronopol, Disodium EDTA, Phenoxyethanol, Benzophenone 3, Citric Acid.

Label



HOME FORMATION ANTIBACTERIAL COCONUT

benzalkonium chloride liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68121-008 |
| 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 |
|--|----------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| COCO MONOETHANOLAMIDE (UNII: C80684146D) | |
| PEG-150 DISTEARATE (UNII: 6F36Q0I0AC) | |
| BRONOPOL (UNII: 6PU1E16C9W) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| BENZOPHENONE (UNII: 701M4TTV9O) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| WATER (UNII: 059QF0KO0R) | |

GLYCOL DISTEARATE (UNII: 13W7MDN21W)

LAURETH-10 (UNII: BD7AST04GA)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68121-008-01 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/02/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 02/02/2021 | |

Labeler - PATCOS COSMETICS (INDIA) PRIVATE LIMITED (916169451)

Revised: 2/2021

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