

TOPCARE ANTIBACTERIAL COMPLETE FOAMING HAND- benzalkonium chloride soap

Abaco Partners LLC DBA Surefil

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.

TopCare ® Antibacterial Complete Foaming Hand Soap

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Uses

for handwashing, reduces germs on the skin

Warnings

For external use only-hands only

When using this product

- Avoid contact with eyes. In case of contact, rinse eyes thoroughly 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.

Directions

- Pump into to dry hands, vigorously work into a lather and rinse thoroughly.

Inactive ingredients

Purified Water, Lauramine Oxide, Glycerin, Cocamidopropyl Betaine, Isostearamidopropyl Ethyldimonium Ethosulfate, Fragrance, DMDM Hydantoin, Tetrasodium EDTA, Hydroxypropyl Methyl Cellulose, Chlorhexidine Gluconate, Zinc Sulfate Monohydrate, Citric Acid, FD&C Red #4 (CI14700), FD&C Yellow #5 (CI19140)

Other information

store at 20°C - 25°C (68°F - 77°F)

Questions?

Call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 221 mL Bottle Label

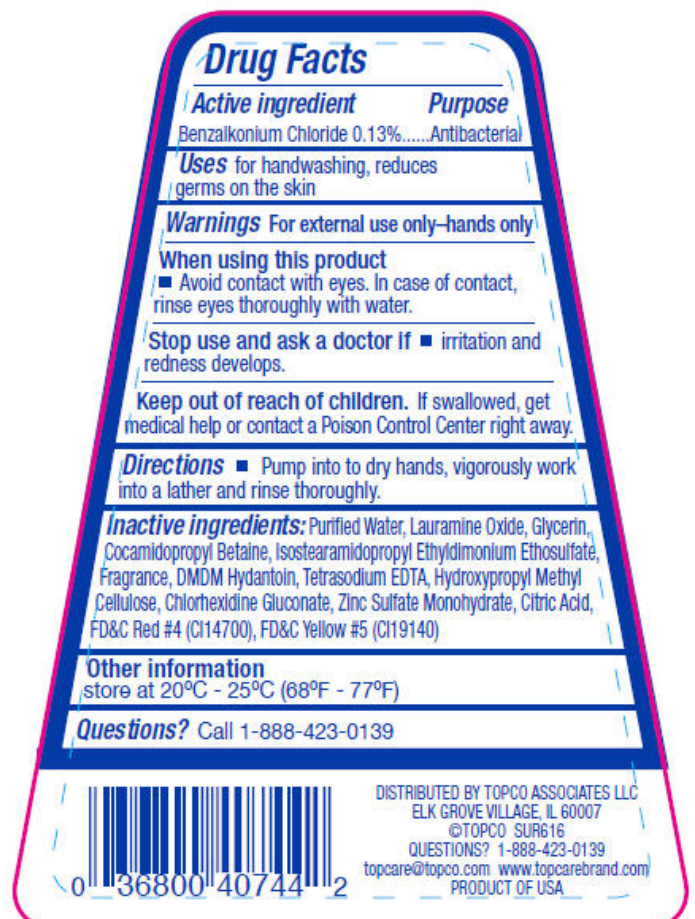
Top Care®

ANTIBACTERIAL
**foaming
hand soap**

gentle enough
for every day

COMPLETE

7.5 FL OZ (221 mL)



TOPCARE ANTIBACTERIAL COMPLETE FOAMING HAND

benzalkonium chloride soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:20890-0140 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 13 mg in 10 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| LAURAMINE OXIDE (UNII: 4F6FC4MI8W) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| ISOSTEARAMIDOPROPYL ETHYLDIMONIUM ETHOSULFATE (UNII: U059JNZ17L) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) | |
| ZINC SULFATE MONOHYDRATE (UNII: PTX099XS F1) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | orange | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:20890-0140-1 | 221 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/01/2016 | |
| 2 | NDC:20890-0140-2 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 08/01/2016 | |

Labeler - Abaco Partners LLC DBA Surefil (964809417)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------------|---------|-----------|-------------------------|
| Abaco Partners LLC DBA Surefil | | 964809417 | manufacture(20890-0140) |

Revised: 12/2021

Abaco Partners LLC DBA Surefil