**FRESH PROTECT SKIN SANITIZER- benzalkonium chloride liquid**
**Omega Tech Labs 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.*

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**Fresh Protect Skin Sanitizer Foam**

## DRUG FACTS

### Active Ingredient

Benzalkonium chloride 0.1%

### Purpose

Antiseptic

### Uses

For hand sanitizing. To decrease bacteria on the skin.

### Warnings

**For external use only.**

**Do not use**

in the eyes. In case of eye contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor**

if irritation or redness develops, or if condition persists more than 72 hours.

**Keep out of reach of children.**

Instruct children on proper use. If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

Apply a small amount on your hands. Rub hands together until dry. When hands are visibly soiled, wash with soap and water.

### Inactive Ingredients

Water, Aloe Barbadensis Leaf Extract, Glycerin, Citrus Grandis (Grapefruit) Seed Extract, Thymus Vulgaris (Thyme) Extract, Camellia Sinensis Leaf (Green Tea) Extract, Avena Sativa (Oat) Extract, Peppermint Essential Oil, Polysorbate 20, Potassium Sorbate, Sodium Benzoate.

## PRINCIPAL DISPLAY PANEL

Fresh Protect
99.9% Natural

Skin Sanitizer Foam
Kills 99.99% of Germs
No Alcohol
7.5 fl. oz. (222 ml)


# FRESH PROTECT SKIN SANITIZER

benzalkonium chloride liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:20802-1501 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.001 g in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PUMMELO** (UNII: ET1TN5W71X) | |
| **THYMUS VULGARIS LEAF** (UNII: GRX3499643) | |
| **GREEN TEA LEAF** (UNII: W2ZU1RY8B0) | |
| **AVENA SATIVA LEAF** (UNII: 206PI19V7R) | |
| **PEPPERMINT OIL** (UNII: AV092KU4JH) | |
| **POLYSORBATE 20** (UNII: 7T1F30V5YH) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:20802-1501-1 | 50 mL in 1 BOTTLE | | |
| **2** | NDC:20802-1501-2 | 222 mL in 1 BOTTLE | | |
| **3** | NDC:20802-1501-3 | 800 mL in 1 BAG | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH NOT FINAL | part333A | 12/16/2010 | |

# FRESH PROTECT SKIN SANITIZER

benzalkonium chloride liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:20802-1503 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.001 g in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

| | |
|---|---|
| **PUMMELO** (UNII: ET1TN5W71X) | |
| **THYMUS VULGARIS LEAF** (UNII: GRX3499643) | |
| **GREEN TEA LEAF** (UNII: W2ZU1RY8B0) | |
| **AVENA SATIVA LEAF** (UNII: 206PI19V7R) | |
| **PEPPERMINT OIL** (UNII: AV092KU4JH) | |
| **POLYSORBATE 20** (UNII: 7T1F30V5YH) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:20802-1503-1 | 3785 mL in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH NOT FINAL | part333A | 12/16/2010 | |

## Labeler - Omega Tech Labs Inc. (019313817)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Omega Tech Labs Inc | | 019313817 | MANUFACTURE |

Revised: 1/2011 Omega Tech Labs Inc.