**FOAMY BLUE- benzalkonium chloride solution**
**Whisk Products, 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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**Foamy Blue**

## Active Ingredient

Benzalkonium Chloride 0.1%

## Purpose

Skin Antimicrobial

## Use

reduces amount of bacteria on hands

## Warnings

For external use only.

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

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

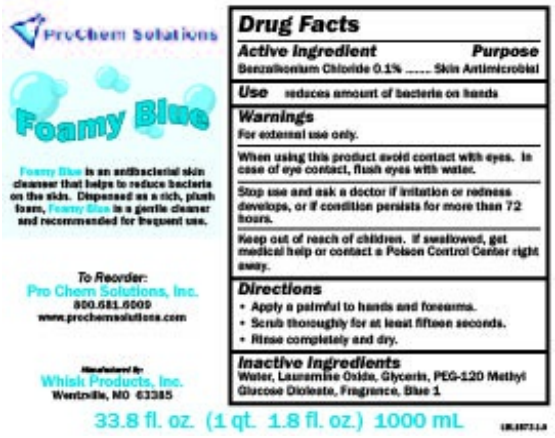
Keep out of reach of children.  If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Apply a palmful to hands and forearms.
- Scrub thoroughly for at least fifteen seconds.
- Rinse completely and dry.

## Inactive Ingredients

Water, Lauramine Oxide, Glycerin, PEG-120 Methyl Glucose Dioleate, Fragrance, Blue 1




# FOAMY BLUE

benzalkonium chloride solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:65585-526 |
| **Route of Administration** | TOPICAL | | |

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

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **LAURAMINE OXIDE** (UNII: 4F6FC4MI8W) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PEG-120 METHYL GLUCOSE DIOLEATE** (UNII: YM0K64F20V) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | blue (dispensed as a light blue foam) | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:65585-526-01 | 800 mL in 1 BAG; Type 0: Not a Combination Product | 01/18/2023 | 01/18/2023 |

| | | | | |
|---|---|---|---|---|
| **2** | NDC:65585-526-02 | 1000 mL in 1 BAG; Type 0: Not a Combination Product | 01/18/2023 | 01/31/2025 |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333E | 01/18/2023 | 01/31/2025 |

## Labeler - Whisk Products, Inc. (834270639)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Whisk Products, Inc. | | 834270639 | manufacture(65585-526) |

Revised: 2/2023 Whisk Products, Inc.