WHISKCARE 387- benzalkonium chloride soap 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.

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 irritaiton 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, Yellow 5, Blue 1

WhistcCare 387 is a FOAMING antibacterial skiin cleanser that helps to reduce bacteria on the skin... It is an economical hand soap that is a gentle cleaner for frequent use.

WhistoCare 387 is triclosam free.



Whisk Products, Inc. Wentzville, MO 63385 www.whiskgonolcluctbs...com



WHISKCARE 387

benzalkonium chloride soap

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HUMAN OTC DRUG NDC:65585-583 Product Type Item Code (Source)

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 | | | |
| LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | | |
| PEG-120 METHYL GLUCO SE DIO LEATE (UNII: YM0 K64F20 V) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |

| Product Characteristics | | | |
|-------------------------|---|--------------|--|
| Color | green (apple green (dispensed as a white foam)) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | Packaging | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:65585-583- 01 | 50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/31/2017 | | |
| 2 | NDC:65585-583- 02 | 6 in 1 BOX | 08/31/2017 | | |
| 2 | | 1000 mL in 1 BAG; Type 0: Not a Combination Product | | | |
| 3 | NDC:65585-583- 03 | 8 in 1 BOX | 08/31/2017 | | |
| 3 | | 1000 mL in 1 BAG; Type 0: Not a Combination Product | | | |
| 4 | NDC:65585-583- 04 | 6 in 1 BOX | 08/31/2017 | | |
| 4 | | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | | |
| 5 | NDC:65585-583- 05 | 6 in 1 BOX | 08/31/2017 | | |
| 5 | | 1750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | | |
| 6 | NDC:65585-583- 06 | 4 in 1 BOX | 08/31/2017 | | |
| 6 | | 4000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | | |
| 7 | NDC:65585-583- 07 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/31/2017 | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part333E | 08/31/2017 | | |
| | | | | |

Labeler - Whisk Products, Inc. (834270639)

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Whisk Products, Inc. | | 834270639 | manufacture(65585-583) |

Revised: 5/2018 Whisk Products, Inc.