WIPE OUT ANTIBACTERIAL WIPES FRESH SCENT- benzalkonium chloride solution TZUMI INNOVATIONS LLC

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.

Zhejiang Qimei, Style 9516, 9599, Fresh Scent

NA

Active Ingredient(s)

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

To decrease bacteria on the skin that could cause disease

Warnings

For external use only

When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water.

Avoid contact with broken skin

Stop use and ask a doctor if irritation and redness develop, 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

Wet hands thoroughly with product and allow to dry without wiping

For children under 6, use only under adult supervision

Not recommended for infants

Other information

- Keep containers tightly closed in a dry, cool and well ventilated place
- Recommended storage temperature: 32F to 104F (0C to 40C)

Inactive ingredients

Aloe Barbadensis Leaf Juice, Water, Fragrance, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Tocopheryl Acetate

| FILE NAME9599-Wipe-Out Antibacterial Wipes-Fresh Scent | | COLORS | PKG DETAILS | |
|--|------------------------|---|-----------------|--|
| BRAND: Wipe-Out | DIMENSIONS: | COMMENTS: | | |
| ITEM#:9599 | MATERIALS: | To FTY: please make adjustments as necessary | | |
| PKG TYPE: Plastic wrap | | REVISION DETAILS | 4 Color Process | |
| | | Update Drug facts information Removed "14.8 oz(420a)" | 7 000 110000 | |
| DATE: 06/02/2020 | DO NOT PRINT: Die Line | Change graphic of "80 WIPES" | | |
| DESIGNER: James | | | | |



ACTUAL SIZE SHOWN



WIPE OUT ANTIBACTERIAL WIPES FRESH SCENT

benzalkonium chloride solution

| Product Information | | | | |
|---------------------|-------------------------|----------------|--------------------|---------------|
| | Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77878-002 |
| | Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | | |
|---|--------------------------|----------|--|--|--|
| Ingredient Name | Basis of Strength | Strength | | | |
| BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y) | BENZALKONIUM CHLORIDE | 6.8 mg | | | |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| WATER (UNII: 059QF0KO0R) | | | | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | | | | |
| POLYSORBATE 20 (UNII: 7T1F30 V5YH) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| PHENO XYETHANOL (UNII: HIE492ZZ3T) | | | | |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) | | | | |

| P | ackaging | | | |
|---|------------------|--|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:77878-002-01 | 20 in 1 BAG; Type 0: Not a Combination Product | 06/25/2020 | |

| 2 NDC:77878-002-02 80 in 1 CANISTER; Type 0: Not a Combination Product 06/25/2020 | | | | |
|---|--|----------------------|--------------------|--|
| | | | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not fina | part333A | 06/25/2020 | | |
| | | | | |

Labeler - TZUMI INNOVATIONS LLC (117426322)

| Establishment | | | | |
|-----------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Zhejiang Qimei Commodity Co.,Ltd. | | 544331136 | manufacture(77878-002) | |

Revised: 6/2020 TZUMI INNOVATIONS LLC