

ANTIBACTERIAL HAND WASH- benzalkonium chloride 0.13% liquid
Vi-Jon, 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.

Drug facts

claims

germ-X

Professional

ALCOHOL FREE

FOAMING HAND SANITIZER

ACTIVE INGREDIENTS

Benzalkonium chloride 0.13%

Purpose

Antiseptic

Use

to decrease bacteria on the skin

Warnings

For external use only: hands only

When using this product

- avoid contact with the eyes. If contact occurs, rinse eyes with water
- avoid contact with broken skin

Stop use and ask a doctor if

- irritation or redness develops
- 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 products and allow to dry without wiping
- for children under 6, use only with adult supervision
- not recommended for infants

other information

- do not store above 105°
- may discolor some fabrics
- harmful to wood finishes and plastics

Inactive ingredients

cetrimonium chloride, diglycerol, disodium cocamphodiacetate, fragrance, glycerin, hydrochloric acid, methoxy PEG/PPG-7/3 aminopropyl

dimethicone, methylchloroisothiazolinone, methylisothiazolinone, tetrasodium EDTA, Water

claims

Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds

Adverse Reactions

Manufactured By: Vi-Jon, Inc.

8515 Page Ave

St. Louis, MO 63114

vijonprofessional.com

391.000/391AA

principal display panel

germ-X

Professional

ALCOHOL FREE

FOAMING

HAND SANITIZER

Kills 99.9% of Germs

Moisturizing

128 FL OZ (1 GAL) 3.79



ALCOHOL FREE FOAMING HAND SANITIZER

Kills 99.99% of Germs*
Moisturizing

128 FL OZ (1 GAL) 3.79

ANTIBACTERIAL HAND WASH

benzalkonium chloride 0.13% liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11344-391 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.313 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP) | |
| DIGLYCERIN (UNII: 3YC120743U) | |
| DISODIUM CO CO AMPHODIACETATE (UNII: 18L9G3U51M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| METHOXY PEG/PPG-7/3 AMINOPROPYL DIMETHICONE (UNII: 4M7P1JZ2V2) | |

| | |
|--|--|
| METHYLCHLORO ISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:11344-391-04 | 750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |
| 2 | NDC:11344-391-45 | 1150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |
| 3 | NDC:11344-391-44 | 532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |
| 4 | NDC:11344-391-46 | 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |
| 5 | NDC:11344-391-05 | 207 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |
| 6 | NDC:11344-391-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |
| 7 | NDC:11344-391-08 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/28/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/28/2016 | |

Labeler - Vi-Jon, Inc (150931459)

Registrant - Vi-Jon, Inc (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|------------------------|
| Vi-Jon. nc | | 150931459 | manufacture(11344-391) |