

**HAND WASH- benzalkonium chloride liquid
Permatex**

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.

**Antibacterial Hand Soap
628.002/628AD/AE**

Active ingredient

Benzalkonium chloride 0.13%

purpose

Antibacterial

Use

for handwashing to decrease bacteria on the skin

warnings

For external use only: hands only

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

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

- apply palmful to dry hands
- scrub thoroughly
- rinse thoroughly

Inactive ingredients

water, cocamidopropyl betaine, lauramidopropylamine oxide, lauramine oxide, myristamidopropylamine oxide, glycerin, fragrance, citric acid, tetrasodium EDTA, benzophenone-4, sodium benzoate, blue 1, red 33

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Solon, OH 44139/ Assembled in U.S.A. with U.S. and global materials

www.permatex.com

628.000/628AA

Principal display panel

Fast Orange

ANTIBACTERIAL FOAMING HAND SOAP

Fresh Scent

Helps kill harmful germs

Gentle enough for everyday use

7.5 FL OZ (221 mL)



HAND WASH

benzalkonium chloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70616-628 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 1.3 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV) | |
| LAURAMINE OXIDE (UNII: 4F6FC4MI8W) | |
| MYRISTAMIDOPROPYLAMINE OXIDE (UNII: 3HSF539C9T) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| SULISOBENZONE (UNII: 1W6L629B4K) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70616-628-96 | 221 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 12/20/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 12/20/2019 | |

Labeler - Permatex (964477025)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(70616-628) |

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| Vi-Jon, LLC | | 790752542 | manufacture(70616-628) |