**FOAMING HAND SANITIZER - benzalkonium chloride gel**
**HY-VEE 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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**DRUG FACTS**

**ACTIVE INGREDIENT**

BENZALKONIUM CHLORIDE 0.1 PERCENT

**PURPOSE**

ANTIMICROBIAL

**USES**

TO HELP REDUCE BACTERIA ON THE SKIN THAT COULD CAUSE DISEASE. RECOMMENDED FOR REPEATED USE.

**WARNINGS**

FOR EXTERNAL USE ONLY.

**WHEN USING THIS PRODUCT**

AVOID CONTACT WITH EYES. IF PRODUCT GETS INTO EYES, RINSE THOROUGHLY WITH WATER.

**STOP USING THIS PRODUCT AND ASK DOCTOR IF**

IRRITATION OR RASH DEVELOPS AND LASTS.

**KEEP OUT OF REACH OF CHILDREN**

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

**DIRECTIONS**

PUMP DESIRED AMOUNT ONTO HANDS AND RUB UNTIL YOUR SKIN IS DRY. CHILDREN UNDER THE AGE OF 6 SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.

**INACTIVE INGREDIENTS**

WATER, POLYSORBATE 20, ETHYLHEXYL METHOXYCINNAMATE, BUTYL METHOXYDIBENZOYLMETHANE, ETHYLHEXYL SALICYLATE, PPG-26-BUTETH-26, PEG-40 HYDROGENATED CASTOR OIL, ALOE BARBADENSIS LEAF JUICE, FRAGRANCE, TETRASODIUM EDTA, DMDM HYDANTOIN, SODIUM HYDROXIDE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140).

**QUESTION OR COMMENTS**

1-800-289-8343

**Front and back labels**


## FOAMING HAND SANITIZER

benzalkonium chloride gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:42507-240 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.1 mL in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **POLYSORBATE 20** (UNII: 7T1F30V5YH) | |
| **OCTINOXATE** (UNII: 4Y5P7MUD51) | |
| **AVOBENZONE** (UNII: G63QQF2NOX) | |
| **OCTISALATE** (UNII: 4X49Y0596W) | |
| **POLYOXYL 40 HYDROGENATED CASTOR OIL** (UNII: 7YC686GQ8F) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **GREEN TEA LEAF** (UNII: W2ZU1RY8B0) | |
| **EDETATE SODIUM** (UNII: MP1J8420LU) | |
| **DMDM HYDANTOIN** (UNII: BYR0546TOW) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:42507-240-08 | 236 mL in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333E | 10/24/2011 | |

## Labeler - HY-VEE INC (006925671)

## Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| APOLLO HEALTH AND BEAUTY CARE | | 201901209 | manufacture |

Revised: 10/2011 HY-VEE INC