INSTANT FOAM HAND SANITIZER ALOE- benzalkonium chloride gel CVS PHARMACY

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

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 CONTACT OCCURS, RINSE WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR REDNESS 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 ENOUGH PRODUCT IN YOUR PALM TO THOROUGHLY COVER YOUR HANDS, RUB TOGETHER UNTIL DRY.

QUESTION OR COMMENTS

1-800-746-7287

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).







INSTANT FOAM HAND SANITIZER ALOE

benzalkonium chloride gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-252

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM UNII:7N6JUD5X6Y)

BENZALKONIUM
CHLORIDE

0.1 mL
in 100 mL

| T . 11 . AT | G |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| OCTINOXATE (UNII: 4Y5P7MUD51) | |
| AVOBENZONE (UNII: G63QQF2NOX) | |
| OCTISALATE (UNII: 4X49 Y0596W) | |
| CASTOR OIL (UNII: D5340 Y219 G) | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | |
| .ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N) | |
| EDETATE SO DIUM (UNII: MP1J8420LU) | |
| DMDM HYDANTO IN (UNII: BYR0546 TOW) | |
| 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:59779-252-02 | 50 mL in 1 BOTTLE | | | | |

| Marketing Information | | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph not final | part333E | 05/18/2011 | | | | |
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Labeler - CVS PHARMACY (062312574)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

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

Revised: 5/2011 CVS PHARMACY