

**HAND SANITIZER- benzalkonium chloride lotion
Humphreyline**

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

benzalkonium chloride (0.13%)

antimicrobial

Hand sanitizer to help reduce bacteria on the skin

For external use only

Do not use in or near the eyes

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed contact a doctor or Poison Control Center right away

Wet hands thoroughly with product and allow to dry without wiping

Keep out of reach of children. If swallowed contact a doctor or Poison Control Center right away.

Water, cetearyl alcohol, petrolatum, behenamidopropyl dimethylamine lactate, lauryl laurate, glycerin, glycereth-2-cocoate, dimethicone, benzoic acid

LOTION SANITIZER
0.5 fl. oz. (15 ml.)

HAND SANITIZER

benzalkonium chloride lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:19392-500 |
| 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 g in 1000 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| BEHENAMIDOPROPYL DIMETHYLAMINE BEHENATE (UNII: 96T33VV28E) | |
| LAURYL LAURATE (UNII: GPW77G0937) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERETH-2 COCOATE (UNII: JWM00VS7HC) | |

DIMETHICONE (UNII: 92RU3N3Y1O)

BENZOIC ACID (UNII: 8SKN0B0MIM)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------|----------------------|--------------------|
| 1 | NDC:19392-500-02 | 15 g in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:19392-500-03 | 30 g in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 01/01/2014 | |

Labeler - Humphreyline (122539042)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|---------------------|
| Humphreyline | | 122539042 | pack(19392-500) |

Revised: 12/2013

Humphreyline