

BERKLEY JENSEN- benzalkonium chloride soap
Apollo Health and Beauty Care

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.

Berkley Jensen Antibacterial Liq Hand Soap

Active Ingredient.

Benzalkonium Chloride (0.13%)

Purpose

Antibacterial

Uses

Helps eliminate bacteria on hands.

Warnings

For external use only

When using this product

Avoid contact with eyes. If this occurs, rinse thoroughly with water.

Stop use and ask a doctor if

irritation or redness develops and lasts

Keep out of reach of children.

In case of accidental ingestion, seek medical attention or contact a poison center immediately.

Directions

- Apply a small amount onto wet hands
- Work into a lather and rinse

Other Information

Store at room temperature

Inactive Ingredients

Water (Aqua), Lauramidopropylamide Oxide, Glycerin, Cetrimonium Chloride, Sodium Chloride, Cocamide MEA, PEG - 120 Methyl Glucose Dioleate, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Red 40 (CI 16035), Yellow 5 (CI 19140), Red 33 (CI 17200),

Principal Display Panel



BERKLEY JENSEN

benzalkonium chloride soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63148-350 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------|------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 130 mg in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SODIUM SULFATE (UNII: 0YPR65R21J) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| WATER (UNII: 059QF0KO0R) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V) | |
| FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| COCO MONOETHANOLAMIDE (UNII: C80684146D) | |
| BASIC YELLOW 5 (UNII: 07BP340B4T) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

Product Characteristics

| | | | |
|-----------------|--|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63148-350-11 | 333 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/15/2022 | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 08/15/2022 | |

Labeler - Apollo Health and Beauty Care (201901209)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------|
| Apollo Health and Beauty Care | | 201901209 | manufacture(63148-350) |

Revised: 8/2022

Apollo Health and Beauty Care