HDX ANTIBACTERIAL HAND- benzalkonium chloride liquid Apollo Health and Beauty Care 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.

Drug Facts

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. In case of contact, 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, get medical help or contact a Poison Control Center immediately.

Directions

- use to refill a hand soap pump bottle
- from pump bottle, apply onto wet hands
- lather and rinse thoroughly

Other information

store at room temperature

Inactive ingredients

Water (Aqua), Lauramidopropylamine 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).

Questions or comments?

Label Copy





HDX ANTIBACTERIAL HAND

benzalkonium chloride liquid

| Product | Information |
|---------|--------------------|
| rivuuci | IIIIVI IIIA UVII |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63148-200

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

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

BENZALKONIUM
CHLORIDE

1.3 mg
in 1 mL

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| WATER (UNII: 059QF0KO0R) | | | |
| LAURAMIDO PRO PYLAMINE O XIDE (UNII: 16 KX160 QTV) | | | |
| GLYCERIN (UNII: PDC6 A3C0 O X) | | | |
| CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5 IBP) | | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| COCO MONOETHANOLAMIDE (UNII: C80684146D) | | | |
| PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V) | | | |
| CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP) | | | |
| EDETATE SO DIUM (UNII: MP1J8420LU) | | | |

| SODIUM SULFATE (UNII: 0 YPR6 5R21J) | |
|--|--|
| METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |

| Pac | kaging | | | |
|-----|---------------|---|-------------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 N | DC:63148-200- | 3785 mL in 1 PACKAGE; Type 0: Not a Combination Product | 0 2/2 1/2 0 19 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333E | 0 2/21/20 19 | |
| | | | |

Labeler - Apollo Health and Beauty Care Inc. (201901209)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

| Establishment | | | | |
|------------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Apollo Health and Beauty Care Inc. | | 201901209 | manufacture(63148-200) | |

Revised: 2/2019 Apollo Health and Beauty Care Inc.