

HY5 ALCOHOL FREE FRAGRANCE FREE FOAMING HAND SANITIZER - benzalkonium chloride liquid
Deb USA, 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

For hand sanitizing to reduce bacteria on the skin

Warnings

For external use only

When using this product avoid contact with eyes. In case of eye contact, flush with water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply one shot to dry hands, rub into skin

No rinsing required

Inactive ingredients

Water, Propylene Glycol, Aloe Barbadensis Leaf Juice, Cocamidopropyl Betaine, Lauramine Oxide, Tetrasodium EDTA, Magnesium Nitrate, Methylchloroisothiazolinone, Magnesium Chloride, Methylisothiazolinone

Hy5 Alcohol Free Hand Sanitizer

Alcohol Free Fragrance Free Foaming Hand Sanitizer

55833

Manufactured for

DermaCare, Inc.

P.O. Box 25263, Sarasota, FL 34277

Ph: 1-877-hy5-5678

www.hy5sanitizer.com

1200 mL 40.6 Fluid Ounces

Rev. 08-11



• Alcohol-Free Hand Sanitizer •

Alcohol-Free Fragrance-Free Foaming Hand Sanitizer

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HY5 ALCOHOL FREE FRAGRANCE FREE FOAMING HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11084-138

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|-------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.13 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| LAURAMINE OXIDE (UNII: 4F6FC4MI8W) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| MAGNESIUM NITRATE (UNII: 77CBG3UN78) | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:11084-138-12 | 1200 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 08/15/2011 | |

Labeler - Deb USA, Inc. (607378015)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|---------------------|
| Deb USA, Inc. | | 607378015 | manufacture |

Revised: 8/2011

Deb USA, Inc.