**HAND-E-FOAM- otc antimicrobial drug products aerosol, foam**
**DermaRite Industries, LLC**

*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.*

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**DRUG LISTING: HAND-E-FOAM**

**Active Ingredient:**

Benzethonium Chloride 0.20%

**Purpose:**

Antiseptic Handwash

**Uses:**

- **Hand sanitizer:** Helps reduce bacteria on skin that could cause disease. Recommended for repeated use.
- **First aid** to help protect against skin infection in minor cuts, scrapes, burns.

**Warnings:**

- **For external use only.**
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- **When using this product** do not apply to large area of raw or blistered skin in large quantities; do not use in or near the eyes.
- **Ask a doctor before use if you have** , deep of puncture wounds, animal bites, serious burns

**Warnings**

- **Keep out of reach of children**. In case of accidental ingestion contact a physician or Poison Control Center right away

**Directions:**

- **Hand sanitizer:** Wet hands thoroughly with product and allow to dry without wiping. Children should be supervised when using this product.
- **First Aid:** Clean the affected area whenever possible. Apply to affected area not more than 3 to 4 times daily. May be covered with a sterile bandage:if bandaged, let dry first.

**Other Information:**

Store at room temperature (59°-86°F)

**Inactive Ingredients:**

Benzalkonium Chloride, Cetrimonium Chloride, Diazolidinyl Urea, Fragrance, Glycerin, Hydroxethyl Cetyldimonium Phosphate, Methylchloroisothiazolinone, Methylisothiazolinone, Methylparaben, PEG-40 Dimethicone, PEG-40 Hydrogenated Castor Oil, PEG-8 Ricinoleate, Propylene Glycol, Propylparaben, Sodium Hydroxide, Tocopheryl Acetate, Water

**Hand-E-Foam Package Label Principal Display Panel**

NDC 61924-102-34

# Hand-E-Foam™

ALCOHOL-FREE FOAMING
HAND SANITIZER
with VITAMIN E

**Drug Facts**

**Active Ingredient** — **Purpose**
Benzethonium Chloride 0.20% ..... First Aid Antiseptic/ Antibacterial

**Uses** **Hand sanitizer:** Helps reduce bacteria on the skin that could cause disease. Recommended for repeated use.
**First aid** to help protect against skin infection in minor:
▪ cuts ▪ scrapes ▪ burns

**Warnings**
**For external use only.**
**Avoid contact with eyes.** In case of contact, flush thoroughly with water.
**When using this product** ▪ do not apply to large areas of raw or blistered skin in large quantities ▪ do not use in or near the eyes.
**Ask a doctor before use if you have** ▪ deep or puncture wounds ▪ animal bites ▪ serious burns.
**Keep out of reach of children.** In case of accidental ingestion contact a physician or Poison Control Center right away.

**Drug Facts** (continued)

**Directions** **Hand sanitizer:** Wet hands thoroughly with product and allow to dry without wiping. Children should be supervised when using this product.
**First aid:** Clean the affected area whenever possible. Apply to affected area not more than 3 to 4 times daily. May be covered with a sterile bandage: if bandaged, let dry first.

**Other Information** Store at room temperature (59°-86°F)

**Inactive Ingredients** Benzalkonium Chloride, Cetrimonium Chloride, Diazolidinyl Urea, Fragrance, Glycerin, Hydroxyethyl Cetyldimonium Phosphate, Methylchlorisothiazolinone, Methylisothiazolinone, Methylparaben, PEG-40 Dimethicone, PEG-40 Hydrogenated Castor Oil, PEG-8 Ricinoleate, Propylene Glycol, Propylparaben, Sodium Hydroxide, Tocopheryl Acetate, Water

DermaRite®

**REORDER #00109F**

34 FL OZ (1000 mL)

DermaRite Industries LLC
Paterson, NJ 07514
1.800.337.6296
www.dermarite.com

MADE IN THE USA

7 14196 10934 7


# Hand-E-Foam™

ALCOHOL-FREE FOAMING
HAND SANITIZER
with VITAMIN E

DermaRite®

**REORDER #00109F**


**CONTENTS: 6 CARTRIDGES - 34 FL OZ (1000 mL) Each**

1 07141 96109344


DermaRite Industries LLC
Paterson, NJ 07514
800.337.6296
www.dermarite.com

MADE IN THE USA


Hand-E-Foam™
ALCOHOL-FREE FOAMING
HAND SANITIZER
with VITAMIN E
DermaRite®
REORDER #00108
CONTENTS: 12 BOTTLES - 8 FL OZ (236 mL) Each
10714196108088
DermaRite Industries LLC
North Bergen, NJ 07047
1.800.337.6296
www.dermarite.com
MADE IN THE USA


Hand-E-Foam™
ALCOHOL-FREE FOAMING
HAND SANITIZER
with VITAMIN E
DermaRite®
REORDER #00102
CONTENTS: 24 BOTTLES - 1.7 FL OZ (50 mL) Each
10714196102024
DermaRite Industries LLC
Paterson, NJ 07514
800.337.6296
www.dermarite.com
MADE IN THE USA


Hand-E-Foam™
ALCOHOL-FREE FOAMING
HAND SANITIZER
with VITAMIN E
LATEX FREE • DERMATOLOGIST TESTED
DermaRite®
NDC 61924-102-17
REORDER #00102
1.7 FL OZ (50 mL)
7 14196 10202 7
MADE IN THE USA
Drug Facts
Active Ingredient
Purpose
Benzethonium Chloride 0.20% ..... First Aid Antiseptic/Antibacterial
Uses Hand sanitizer: Helps reduce bacteria on the skin that could cause disease. Recommended for repeated use. First aid: to help protect against skin infection in minor • cuts • scrapes • burns
Warnings
For external use only.
Avoid contact with eyes. In case of contact, flush thoroughly with water.
When using this product • do not apply to large areas of raw or blistered skin in large quantities • do not use in or near the eyes.
Ask a doctor before use if you have • deep or puncture wounds • animal bites • serious burns
Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.
Directions Hand sanitizer: Wet hands thoroughly with product and allow to dry without wiping. Children should be supervised when using this product. First aid: Clean the affected area whenever possible. Apply to affected area not more than 3 to 4 times daily. May be covered with a sterile bandage: if bandaged, let dry first.
Other Information Store at room temperature (59°-86°F)
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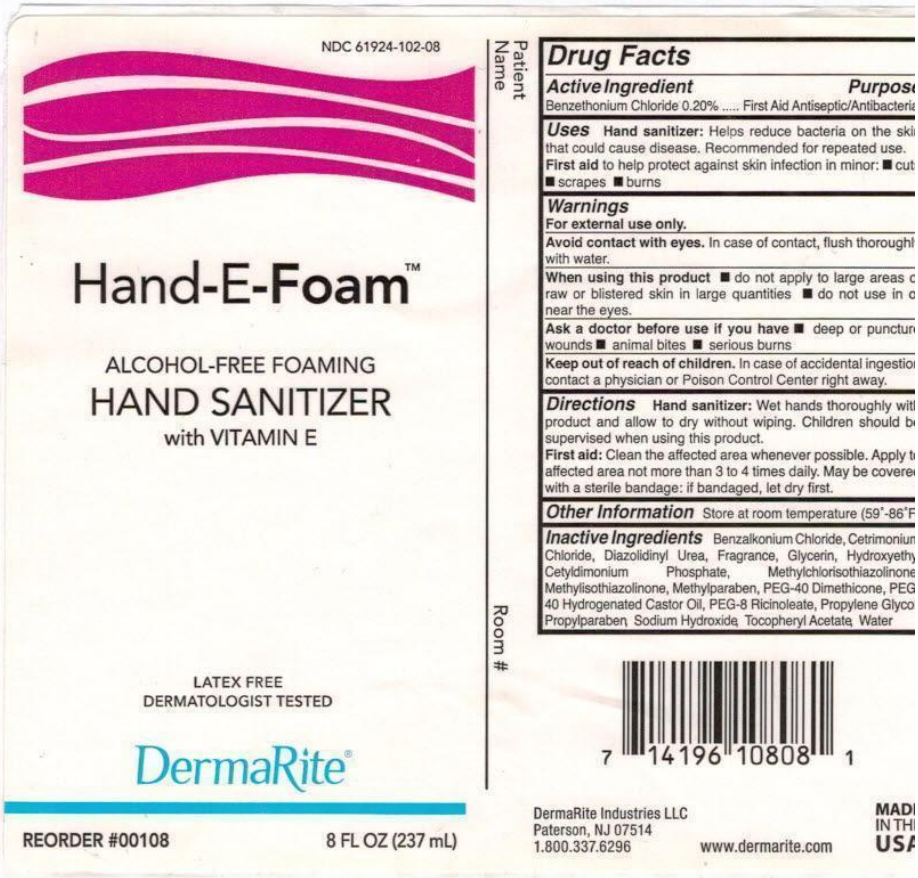
DermaRite Industries LLC • Paterson, NJ 07514
1.800.337.6296 • www.dermarite.com


NDC 61924-102-08
Hand-E-Foam™
ALCOHOL-FREE FOAMING
HAND SANITIZER
with VITAMIN E
LATEX FREE
DERMATOLOGIST TESTED
DermaRite®
REORDER #00108
8 FL OZ (237 mL)
Patient Name
Room #
Drug Facts
Active Ingredient
Purpose
Benzethonium Chloride 0.20% ..... First Aid Antiseptic/Antibacterial
Uses Hand sanitizer: Helps reduce bacteria on the skin that could cause disease. Recommended for repeated use.
First aid to help protect against skin infection in minor: ■ cuts ■ scrapes ■ burns
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7 14196 10808 1
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Paterson, NJ 07514
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MADE IN THE USA

## HAND-E-FOAM

otc antimicrobial drug products aerosol, foam

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:61924-102 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **BENZETHONIUM CHLORIDE** (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP) | BENZETHONIUM CHLORIDE | 0.002 g in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **CETRIMONIUM CHLORIDE** (UNII: UC9PE95IBP) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **HYDROXYETHYL CETYLDIMONIUM PHOSPHATE** (UNII: 9G05UO431K) | |
| **METHYLCHLOROISOTHIAZOLINONE** (UNII: DEL7T5QRPN) | |
| **METHYLISOTHIAZOLINONE** (UNII: 229D0E1QFA) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PEG-8 DIMETHICONE** (UNII: GIA7T764OD) | |
| **POLYOXYL 40 HYDROGENATED CASTOR OIL** (UNII: 7YC686GQ8F) | |
| **PEG-8 RICINOLEATE** (UNII: DM36F4D2OU) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61924-102-08 | 237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/08/2002 | |
| **2** | NDC:61924-102-17 | 50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/08/2002 | |
| **3** | NDC:61924-102-34 | 1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product | 08/08/2002 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 08/08/2002 | |

## Labeler - DermaRite Industries, LLC (883925562)

## Registrant - DermaRite Industries, LLC (883925562)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| DermaRite Industries, LLC | | 883925562 | manufacture(61924-102) |

Revised: 12/2022 DermaRite Industries, LLC