

SAN-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.

DRUG LISTING: SAN-E-FOAM

Active Ingredient:

Ethyl Alcohol 67%

Purpose:

Antiseptic

Uses:

- For handwashing to decrease bacteria on the skin.
- Recommended for repeated use.

Warnings:

For external use only.

Flammable. Keep away from heat or flame.

Avoid contact with eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if skin irritation develops.

In case of accidental ingestion contact a physician or Poison Control Center right away.

Directions

- Wet hands thoroughly with product.
- Briskly rub hands until dry.
- Supervise children in the use of this product.

Other Information

- Do not store above 105°F. May discolor some fabrics or surfaces.
- May report serious adverse events to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047

San-E-Foam Package Label Principal Display Panel

NDC 61924-107-08



San-E-Foam™

FOAMING
HAND SANITIZER
with VITAMIN E

DermaRite®

REORDER #00105

236 mL (8 fl. oz.)

Patient
Name

Room
#

Drug Facts

Active Ingredient	Purpose
Alcohol 67%	Antiseptic

Uses

- For handwashing to decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from heat or flame.

Avoid contact with eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if skin irritation develops.

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

Directions

- Wet hands thoroughly with product.
- Briskly rub hands until dry.
- Supervise children in the use of this product.

Other information ■ Do not store above 105°F ■ May discolor some fabrics or surfaces. ■ You may report a serious adverse event to DermaRite Industries, PO Box 7208, North Bergen, NJ 07047.

Inactive ingredients Water, PEG-10 Dimethicone, Fragrance, t-Butyl Alcohol, Glycerin, Tocopherol Acetate, Denatonium Benzoate

Questions? Call 1-800-337-6296 Mon - Fri 9AM - 5PM EST.

DermaRite Industries LLC
7777 West Side Avenue
North Bergen, NJ 07047
www.dermarite.com

**MADE
IN THE
USA**
101232

SAN-E-FOAM

otc antimicrobial drug products aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-107
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.67 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-107-17	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/12/2012	
2	NDC:61924-107-34	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	10/12/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/12/2012	

Labeler - Dermarite Industries LLC (883925562)

Registrant - Dermarite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
Dermarite Industries LLC		883925562	manufacture(61924-107)

Revised: 1/2020

Dermarite Industries LLC