KLEENFOAM- otc antimicrobial drug product 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: KLEENFOAM

Active Ingredient

Chloroxylenol 0.5%

Purpose:

Antiseptic Handwash

Uses:

- For handwashing to decrease bacteria on the skin.
- after changing diapers;
- after assisting ill persons;
- before contact with a person under medical care or treatmentRecommended for repeated use.

Warnings:

- **For external use only.**
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- **Ask a doctor before use if** you have , deep of puncture wounds, animal bites, serious burns
- **When using this product,** do not apply to areas of raw or blistered skin in large quantities, do not use in or near the eyes
- **Stop use and ask a doctor if**, condition worsens, symptoms last for more than 7 days or clear up and recur within a few days

Warnings:

For external use only.

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

Discontinue use if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

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

Directions:

- Wet hands and forearms.
- Apply 5 millimeters (teaspoon) or palmful to hands and forearms.
- Scrub thoroughly for 15 seconds.
- Rinse and repeat.

Other information:

Store at room temperature (59°-86°F). You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047

Inactive Ingredients:

Water, Sodium Lauryl sulfate, Sodium Laureth Sulfate, Cocamide MEA, Cocamidopropyl Betaine, Polysorbate 20, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben, Disodium EDTA, Sodium Isostearoyl lactylate, Aloe Barbadensis Leaf Juice, Citrus Limon (Lemon) Peel Oil, Citric Acid, Sodium Hydroxide

Question?

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

Kleenfoam Package Label Principal Display Panel

3″ (W) x 4″ (H)

NDC 61924-093-34

KleenFoam™

HEALTH CARE ANTISEPTIC
FOAM SOAP with ALOE VERA

Drug Facts

Active ingredient ***Purpose***
Chloroxylenol 0.5% ..... Antiseptic Handwash

Uses For handwashing to decrease bacteria on the skin: ■ after changing diapers; ■ after assisting ill persons; ■ before contact with a person under medical care or treatment.

Warnings

For external use only.

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

Discontinue use if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

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Drug Facts (continued)

Directions ■ Wet hands and forearms. ■ Apply 5 ml or palmful to hands and forearms. ■ Scrub thoroughly for 15 seconds. ■ Rinse and repeat.

Other information ■ Store at room temperature (59˚-86˚F) ■ You may report a serious adverse event to DermaRite Industries, PO Box 7209, North Bergen, NJ 07047.

Inactive ingredients Water, Sodium Lauryl Sulfate, Sodium Laureth Sulfate, Cocamide MEA, Cocamidopropyl Betaine, Polysorbate 20, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben, Disodium EDTA, Sodium Isostearoyl Lactylate, Aloe Barbadensis Leaf Juice, Citrus Limon (Lemon) Peel Oil, Citric Acid, Sodium Hydroxide

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

DermaRite®

REORDER #0093F

1000 mL (34 fl. oz)

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

MADE IN THE USA
101834

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PMS 2718C

PMS 3125C

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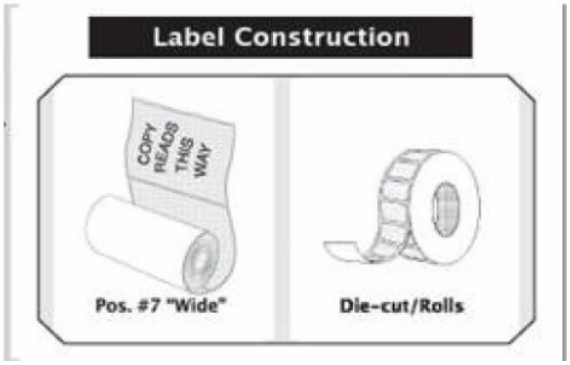

KLEENFOAM

otc antimicrobial drug product aerosol, foam

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61924-093
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.005 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LEMON OIL (UNII: I9GRO824LL)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

COCO MONOETHANOLAMIDE (UNII: C80684146D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-093-34	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	12/12/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/12/2011	

Labeler - Dermarite Industries LLC (883925562)

Registrant - Dermarite Industries LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
Dermarite Industries LLC		883925562	manufacture(61924-093)

Revised: 1/2020 Dermarite Industries LLC