

DERMAKLEEN- antimicrobial drug product soap
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: DERMAKLEEN

Active Ingredient:

Chloroxylenol 0.2%

Purpose:

Antimicrobial

Uses:

For handwashing to decrease bacteria on the skin.

Warnings

- **For external use only.**
- **Avoid contact with eyes.** In case of contact, flush thoroughly with water.
- **Stop use and ask a doctor** if irritation or redness develops.

Warnings

- **Keep out of children's reach** except under adult supervision. In case of accidental ingestion contact a physician or Poison Control Center rightaway.

Directions:

- Dispense into hands, wet as needed.
- Lather vigorously for at least 15 seconds
- Wash skin, rinse thoroughly and dry.


Inactive Ingredients:

Cocamide MEA, Cocamidopropyl Betaine, Citric Acid, DMDM Hydantoin, D&C Green#6, Fragrance, Glycerin, Methylchlorisothiazolinone, Methylparaben, Methylisothiazolinone, Propylene Glycol, Propylparaben, Sodium Chloride, Sodium Hydroxide, Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Tetrasodium EDTA, Tocopheryl Acetate, Water.

Questions?

Call 1-800-337-6296

Dermakleen Package Label Principal Display Panel




NDC 61924-092-08

DermaKleen™

**HEALTH CARE ANTISEPTIC
LOTION SOAP**
with VITAMIN E

Mild on skin

FORMULATED WITHOUT TRICLOSAN



REORDER #0098
222 mL (7.5 fl. oz.)

Patient
Name

Drug Facts

Active ingredient	Purpose
Chloroxylenol 0.2%	Antiseptic

Uses For handwashing to decrease bacteria on the skin.

Warnings
For external use only.
Avoid contact with eyes. In case of contact, flush thoroughly with water.
Stop use if irritation or redness develops. ■ If condition persists for more than 72 hours consult a doctor.
Keep out of reach of children except under adult supervision. In case of accidental ingestion contact a physician or Poison Control Center right away.


Directions ■ Wet hands and forearms. ■ Apply 5 milliliters (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, Propylene Glycol, DMDM Hydantoin, Methylparaben, Propylparaben, Fragrance, Tetrasodium EDTA, Tocopheryl Acetate, Glycerin, Yellow 5, Blue 1, Citric Acid, Sodium Chloride, Sodium Hydroxide

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

Room #



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

**MADE
IN THE
USA**
10132

DERMAKLEEN

antimicrobial drug product soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61924-092
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.002 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
D&C GREEN NO. 6 (UNII: 4QP5U84YF7)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61924-092-08	222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/15/2012	
2	NDC:61924-092-01	3800 mL in 1 JUG; Type 0: Not a Combination Product	06/01/2012	
3	NDC:61924-092-34	1000 mL in 1 BAG; Type 0: Not a Combination Product	06/01/2012	
4	NDC:61924-092-27	800 mL in 1 BAG; Type 0: Not a Combination Product	06/01/2012	
5	NDC:61924-092-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/15/2012	

Labeler - Dermarite Industries LLC (883925562)

Registrant - DermaRite Industries, LLC (883925562)

Establishment

Name	Address	ID/FEI	Business Operations
Dermarite Industries LLC		883925562	manufacture(61924-092)

Revised: 1/2022

Dermarite Industries LLC