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.

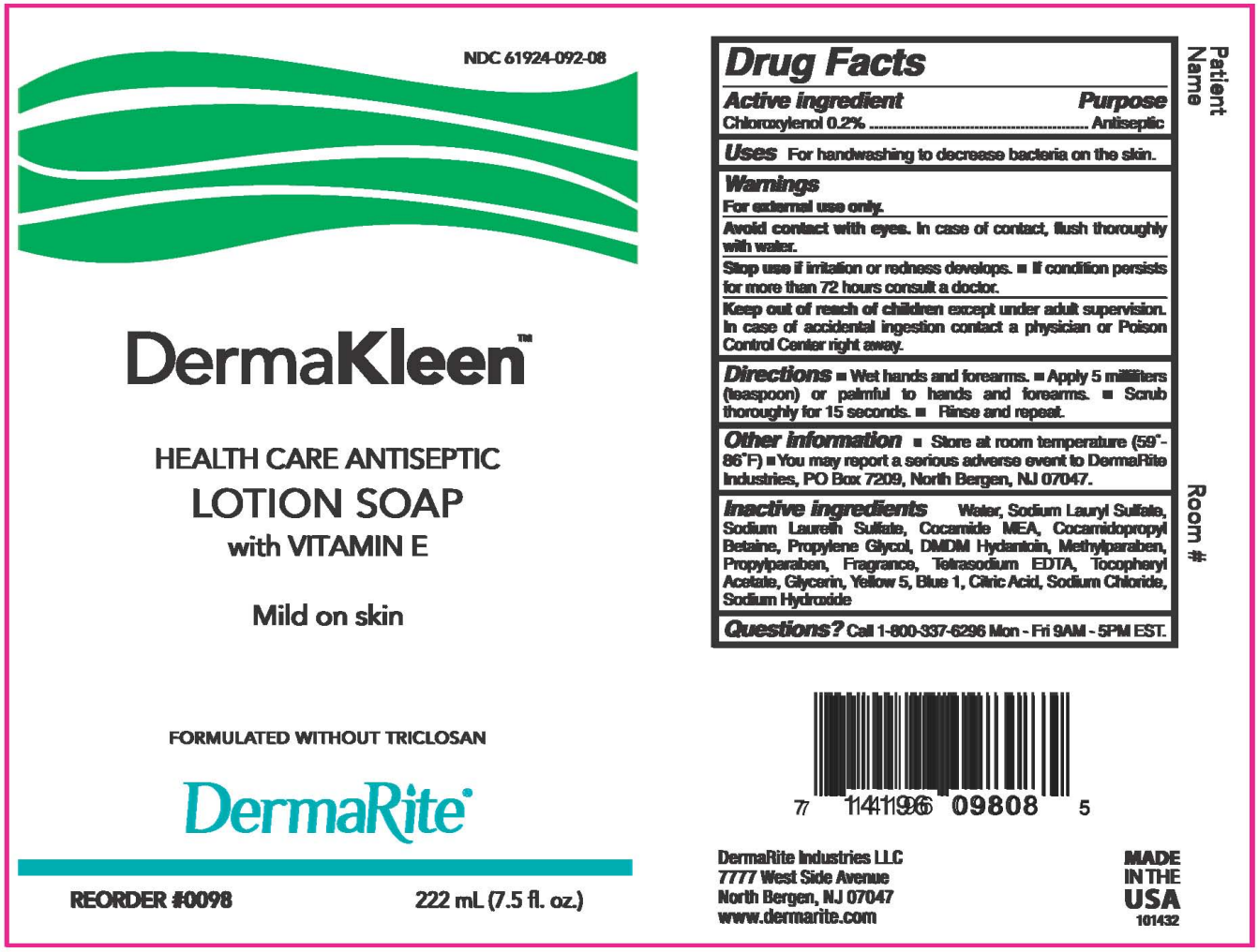
Inactive Ingredients:

Cocamide MEA, Cocamidoproplyl Betaine, Citric Acid, DMDM Hydantoin, D&C Green#6, Fragrance, Glycerin, Methylchloroisothiazolinone, 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



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: 5OCF3O11KX)	
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