

AMERIDERM ANTIBACTERIAL WASH- parachlorometaxylenol liquid SHIELD LINE 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.

AMERIDERM Antibacterial Foaming - ALL-211

Drug Facts

Active Ingredient

Parachlorometaxylenol 0.3% w/w

Purpose

Antiseptic

Uses

- Handwash to help reduce bacteria on the skin that potentially can cause disease
- Recommended for repeat use

Warnings

- **For external use only**
- Keep out of eyes, ears or mouth. In case of eye contact, flush eyes with water
- **Stop use and ask a doctor** if irritation and redness develop or if condition persists for more than 72 hours

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Wet hands with water and dispense sufficient amount of product into cupped palm of hand
- Wash both hands thoroughly for 15 seconds
- Rinse under running water and dry thoroughly

Inactive Ingredients

Citric Acid Monohydrate, Cocamidopropyl Betaine, Coco Diethanolamide, Disodium Laureth Sulfosuccinate, Edetate Disodium Anhydrous, Ethylhexyl Glycerin, Fragrance, Glyceryl oleate, PEG-7 Glyceryl Cocoate, Phenoxyethanol, Sodium Laureth 3 Sulfate,

Sulisobenzone, Water

Package Label

AmeriDerm

Foam Soap™

Antiseptic

NDC: 52410-8073-2

Reorder No: 211

1000 ml (33.8 fl. oz.)

Drug Facts	<i>Keep out of reach of children</i> If swallowed, get medical help or contact a Poison Control Center right away				
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%;">Active ingredient</th> <th style="width: 50%;">Purpose</th> </tr> <tr> <td>Parachlorometaxyleneol 0.3% w/w.....</td> <td>Antiseptic</td> </tr> </table>	Active ingredient	Purpose	Parachlorometaxyleneol 0.3% w/w.....	Antiseptic	Directions
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AMD-80723

Manufactured for:
Shield Line LLC,
Hackensack, NJ 07601, USA
www.shieldline.com

Made in Turkey



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32-8072-3AD-04

AMERIDERM ANTIBACTERIAL WASH

parachlorometaxyleneol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52410-8073
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength
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Ingredient Name		Strength	Strength	
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)		CHLOROXYLENOL	0.003 mg in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)				
GLYCERYL OLEATE (UNII: 4PC054V79P)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
SULISOBENZONE (UNII: 1W6L629B4K)				
WATER (UNII: 059QF0KO0R)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
COCO DIETHANOLAMIDE (UNII: 92005F972D)				
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52410-8073-2	1000 mL in 1 POUCH; Type 0: Not a Combination Product	06/12/2018	
2	NDC:52410-8073-4	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	06/12/2018		

Labeler - SHIELD LINE LLC (078518916)

Revised: 1/2022

SHIELD LINE LLC